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**UNITED STATES DISTRICT COURT**

**DISTRICT OF NEVADA**

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff,

– vs. –

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I – X and ROE CORPORATIONS I – X, inclusive,

Defendants.

Case No. 2:12-cv-01849

**APEXUS, INC.'S MOTION FOR SUMMARY JUDGMENT ON CONDUCT-BASED IMMUNITY AND BRIEF IN SUPPORT**

**ORAL ARGUMENT REQUESTED**

COMES NOW Apexus, Inc., and pursuant to Rule 56 of the Federal Rules of Civil Procedure files this Motion for Summary Judgment and Brief in Support, and would show the Court as follows:

## I. CASE OVERVIEW

Under the doctrine of conduct-based immunity, Apexus, Inc. ("Apexus") is immune from Plaintiff's claims because it is the 340B Prime Vendor and manages the 340B Prime Vendor Program on behalf of the Health Resources and Services Administration ("HRSA"). Apexus is bound by its governing contract with HRSA which includes the obligation to provide non-covered products, such as vaccines, as value added products. Plaintiff claims that Apexus, and the other Defendants, violated the antitrust laws by including vaccines in the 340B Prime Vendor Program, even though the inclusion is in accordance with Apexus's contract with HRSA and even though HRSA had the authority to mandate that the vaccines be included. As the 340B Prime Vendor, Apexus is an instrumentality of the federal government, and is immune from antitrust liability when following the terms of its contract with HRSA. It also cannot be held liable on any of Plaintiff's other claims.

Congress established the 340B Program to leverage covered entities' purchasing power. The statute contemplates that the 340B Program will be managed by a prime vendor. The Department of Health & Human Services ("HHS"), through HRSA and, ultimately, the Office of Pharmacy Affairs ("OPA"), implemented the Prime Vendor Program to administer the 340B Program. OPA did not have the resources to run the 340B Prime Vendor Program, so HRSA outsourced the role of managing the Prime Vendor Program to a private entity.

In 2004, Apexus' predecessor, HPPI, was a subcontractor to the first Prime Vendor Contractor. Later, in subsequent contract rounds, HRSA awarded HPPI, and then Apexus, the Prime Vendor contract directly.

As part of its initial duties under its subcontract with the first Prime Vendor Contractor, Apexus met with Customer Consultation Groups comprised of covered entities. These Customer Consultation Groups voiced a strong request to include vaccines in the 340B Prime Vendor Program, although vaccines were not technically considered covered drugs under the 340B

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Program. In 2004, HRSA, through the OPA, allowed Apexus to include vaccines in the 340B Prime Vendor Program as a value added product to help foster the public health and increase the benefits available under the 340B Program. Subsequently, the solicitation for the 2009 Prime Vendor contract included as a factor the applicant's ability to offer non-covered value added products, including vaccines. When Apexus was selected to manage the Prime Vendor Program in 2009, the agreement by which Apexus was bound required Apexus to offer, among other things, the non-covered items (including vaccines) as per the express terms of the solicitation and the parties' contract.

Plaintiff has alleged claims for violations of the Robinson-Patman Act, 15 U.S.C. § 13(a), common law aiding and abetting, plus several additional common law claims. *Id.* at ¶¶ 48-72. Plaintiff's claims against Defendants are based on the following facts: Apexus, as per its contract with the OPA and HRSA, included vaccines in the 340B Prime Vendor Program; GlaxoSmithKline LLC ("GSK") sold vaccines through the 340B Prime Vendor Program; and Southern Nevada Health District ("SNHD") bought vaccines through the 340B Prime Vendor Program. Further, GSK sold the vaccines and SNHD purchased the vaccines because of their contracts under the 340B Prime Vendor Program.

Plaintiff ignores the following facts, however. OPA, through HRSA and the HHS, is entitled to judicial deference for including vaccines as value added products under the 340B Prime Vendor Program. OPA and HRSA had the authority to fill in the gaps left by Congress for the operation of the 340B Prime Vendor Program. Moreover, OPA and HRSA have the authority to make decisions on the operation of the 340B Prime Vendor Program so long as those decisions are consistent with the intent of the 340B Program.

Accordingly, when Apexus, as the manager of the Prime Vendor Program on behalf of HRSA, negotiates pricing discounts for vaccines as value added products under the 340B Prime Vendor Program, GSK sells at those prices, and SNHD purchases at those prices, they are complying with the OPA's and HRSA's instructions and their respective contractual obligations. Apexus, and indeed all the Defendants, must be immune from claims that their actions violate the

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antitrust laws, and are also immune from the various common law claims in the First Amended Complaint ("FAC").

## II. PROCEDURAL HISTORY

Plaintiff filed this suit on October 25, 2012 and Apexus was served with process on November 7, 2012. (Dkt. #1). Plaintiff also named GSK and SNHD as Defendants, as well as 10 ROE and 10 DOE "Defendants."

Apexus and the other named Defendants filed their respective motions to dismiss on January 18, 2013. (Dkt. #29). The parties also moved to stay discovery pending the ruling on the Motions to Dismiss. (Dkt. #64, #75). The Court granted that motion on April 25, 2013. (Dkt. #96).

The Court held a hearing on the Defendants' Motion to Dismiss on September 12, 2013. The Court denied the pending motions to dismiss and suggested that the parties bifurcate discovery to reduce costs and increase efficiencies. The case was initially bifurcated so that: (1) liability would be addressed first; and (2) then damages would be addressed if the Plaintiff's claims survived summary judgment. Included within the liability phase was the issue of immunity as well as the applicability of the own-use exemption under the Robinson-Patman Act.

After the Court's denial of the Motion to Dismiss, the parties engaged in written discovery and document production. It became apparent to the parties however, that bifurcating discovery to include all of liability would be excessive due to the volume of documents related to antitrust injury, antitrust standing, market definition, competitive impact, and the other factual issues in this case. Further, much of the liability phase discovery does not address the two key issues that could end this case immediately: immunity and the own-use exemption.

Accordingly, the parties submitted a new schedule to the Court that provided for a streamlined schedule limiting discovery and bringing the immunity and own-use issues before the Court as quickly as possible. (Dkt. #150). On June 3, 2014, the Court entered the parties' joint Revised Stipulated Discovery Plan and Scheduling Order. (Dkt. #152). On June 16, 2014, Plaintiff filed its First Amended Complaint against the Defendants (Dkt. #154). Under this Scheduling

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Order Defendants must file their motions for summary judgment related to immunity and own use by July 22, 2014.

## III. LEGAL STANDARD

Summary judgment allows a court to avoid unnecessary trials when no material facts are in dispute. *Northwest Motorcycle Ass'n v. U.S. Dept. Of Agric.*, 18 F.3d 1468, 1471 (9th Cir. 1994). When deciding a motion for summary judgment, the Court must view all evidence and any inferences arising from the evidence in the light most favorable to the nonmoving party. *Bagdadi v. Nazar*, 84 F.3d 1194, 1197 (9th Cir. 1996). The Court should grant summary judgment when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

The moving party has the burden of informing the Court of the basis for its motion and submitting authoritative evidence to demonstrate the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S. Ct. 2548, 91 L. Ed. 265 (1986); *C.A.R. Transp. Brokerage Co., Inc. v. Darden Rest., Inc.*, 213 F.3d 474 (9th Cir. 2000). If the moving party satisfies its initial burden, the burden then shifts to the nonmoving party to establish that a genuine issue of fact exists. *Matshshita Electric Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). The party opposing the motion must then set forth specific facts showing the existence of those material facts. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). The opposing party may not rely on allegations or mere denials. *Id.*

The Court should not weigh evidence or determine the truth of the matter asserted; it must only determine whether there is a genuine issue of material fact. *Summers v. A Teichert & Son, Inc.*, 127 F.3d 1150, 1152 (9th Cir. 1997). For a factual dispute to be genuine there must be enough doubt for a reasonable trier of fact to find for the plaintiff to defeat a defendant's motion for summary judgment. *Addisu v. Fred Meyer, Inc.*, 198 F.3d 1130, 1134 (9th Cir. 2000).

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## IV. FACTUAL BACKGROUND

### A. Brief Description of the Parties.

Plaintiff alleges that it is a medical clinic that provides immunization services to infants, adults, and children for work, school, travel, and general health purposes. *See* Plaintiff's FAC, at ¶ 8.[1] It purchases vaccines for use in its clinic from GSK either directly or through a third-party buying group. *Id.* at ¶ 9.

Apexus does not manufacture or sell vaccines. *Id.* at ¶ 11. Rather, it negotiates pricing programs, establishes distribution solutions to improve access to affordable medications, and provides value added products and services under the 340B Prime Vendor Program administered by HRSA. *Id.* The OPA is an office within HRSA. Further, HRSA is a division within HHS.

GSK provides covered drugs and vaccines to covered entities through the 340B Program, as well as through other government programs. *Id.* at 15. For example, GSK sells vaccines through the 340B Program as well as through other governmental programs and other distributors, wholesalers and group purchasing organizations.

Defendant SNHD is a participant in the 340B Program. *Id.* at ¶ 18. As a result, SNHD is able to purchase pharmaceuticals from GSK under the terms negotiated by Apexus for all participants in the 340B Program. *Id.* It also is able to purchase additional products, such as vaccines, under the 340B Prime Vendor Program's negotiated prices. *Id.* at ¶¶ 23-25. SNHD also purchases vaccines from GSK and other manufacturers both directly and through other governmental programs.

### B. The Legislative Basis for the 340B Program.

The 340B Program is part of the Veterans Health Care Act of 1992, codified at 42 U.S.C. § 256b. The statute states that "[t]he Secretary [of HHS] shall enter into an agreement with each

[1] For purposes of this summary judgment motion only, Apexus asks the Court to take the allegations in the cited paragraphs of the FAC as true. Defendants' are still entitled to summary judgment on the grounds set forth herein even if the facts in the cited portions in the FAC are true.

manufacturer of covered outpatient drugs . . . ." Under any agreement, the manufacturers agree to price ceilings for certain drugs that are then sold to covered entities that provide health care services to lower-income patients. *Id.* at § 256b(a)(4). To administer this program, the statute provides that the "Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs." *Id.* at § 256b(a)(8).

The legislative history of 42 U.S.C. § 256b also speaks to the Secretary's authority to develop the prime vendor program:

> (d) BID PROCESS.-Not later than 90 days after the date of enactment of this section, the Secretary, in consultation with the Secretary of Veterans Affairs, shall develop and implement a bid process to establish a prime vendor program under which covered entities compensate wholesalers for distribution and related services to facilitate drug purchases to which discounts will apply under this section.

138 Cong. Rec. H11666-02, 138 Cong. Rec. H11666-02, 1992 WL 280143.

Moreover, the legislative history indicates a certain amount of flexibility that the Secretary had in developing the prime vendor program:

> The Committee emphasizes that the bill does not limit the amount of drugs that a "covered entity" may procure for purposes of receiving price reductions under this agreement. . . . The Committee bill does not authorize the Secretary to limit in any way the volume of purchases that can be made at the price reduction provided under the Secretary's agreements with manufacturers.
>
> The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity." ….

H.R. REP. 102-384, *16.

In fulfillment of its obligations under the 340B Program, in 1999 HRSA, through the OPA, established the Prime Vendor Program. A Prime Vendor is selected every five years. In both 2004 and 2009, HRSA selected Apexus as the Prime Vendor. Apexus currently has an exclusive 5 year contract with HRSA's Office of Pharmacy Affairs to serve as the 340B Prime Vendor. *See*

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http://www.hrsa.gov/about/index.html. As a result, Apexus manages the program on behalf of HRSA and the OPA, and has the contractual obligation to negotiate prices on behalf of covered entities with drug manufacturers. Without Apexus, no contracts with manufacturers could be entered into and no covered entities would be able to purchase covered drugs. In other words, Apexus is an instrumentality of the federal government in this role because it fulfills HRSA's obligations under the statutory requirements of the 340B Program to manage the Prime Vendor Program.

**C. Organization and Operation of the Prime Vendor Program.**

Captain Jimmy R. Mitchell of the U.S. Public Health Service Corps (retired) was the original Director of the OPA. *See* Declaration of Captain Jimmy R. Mitchell, attached hereto as **Exhibit D** and incorporated by reference for all purposes. Indeed, Captain Mitchell helped organize the OPA as it exists today. Prior to his arrival, the office was called the Office of Drug Pricing. *Id.* at ¶5. Captain Mitchell decided that the office should be more proactive and should work to provide covered drugs and other value added products to the country's safety net organizations. He wanted the office to have a significant part in delivering the supplies needed to foster public health. Because the mission of the Office of Drug Pricing changed, with HRSA's approval, the Office of Drug Pricing was renamed the Office of Pharmacy Affairs. *Id.*

One of the tasks Captain Mitchell addressed after restructuring the OPA was to implement the 340B Prime Vendor Program. Though Congress had passed enabling legislation for the 340B Program, which called for a prime vendor, it never passed legislation to create a prime vendor. *Id.* at ¶8. The Prime Vendor Program as organized and operated by the Veterans Administration had the same guidelines and purpose as the 340B Prime Vendor. *See* Section 601 of the Veterans Health Care Act of 1992. *Id.* at ¶9. As a result, Captain Mitchell and the OPA relied on the Veterans Administration's rules and regulations in creating a functioning 340B Prime Vendor Program for HRSA. The Prime Vendor Program needed to operate as a public – private partnership, however, because OPA and HRSA did not have the resources that the Veterans

Administration had for its program. *Id.* at ¶10. In all other respects, however, they would operate in essentially the same manner.

**D. Apexus Becomes the Prime Vendor.**

In 1999, in order to implement the 340B Program, and in order to comply with the statutory mandate to establish a Prime Vendor to manage the 340B Prime Vendor Program, the HRSA selected the original Prime Vendor, Amerisource Bergen ("AMB"). *Id.* at ¶11. HRSA selected it because its wide range of products satisfied the demands of the covered entities. AMB, however, lacked the distribution method and structure to negotiate with other distributors to ensure efficient delivery of 340B Prime Vendor Program products to covered entities. *Id.* As a result, in 2004 AMB subcontracted with Apexus[2] to provide logistical know-how regarding effective distribution to the 340B Prime Vendor Program. During its time as a subcontractor, Apexus fulfilled one of the Prime Vendor's obligations to meet with the covered entities and organize Customer Consultation Groups regarding various topics so that the covered entities could voice any requests for additions or changes to the 340B Prime Vendor Program. *Id.* at ¶12. The covered entities overwhelmingly requested that the 340B Prime Vendor Program also include vaccines. *Id.*

Such a request made sense. Covered entities are relatively small, such as state or county health districts, DSH – hospitals, and other non-profit healthcare providers. They do not have the resources that larger for-profit providers do. The ability to purchase discounted vaccines as well as discounted covered drugs would help further the mission of the covered entities and of the 340B Program — to promote public health and serve the poorest members of our community. *Id.* at ¶19.

**E. HRSA Adds Vaccines to the Prime Vendor Program.**

In light of the covered entities' request for vaccines, Apexus asked OPA whether it could include vaccines in the 340B Prime Vendor Program even though vaccines were not specifically included as covered drugs. HRSA, after conferring with its contract procurement group and OPA's

[2] At that time, Apexus was known by its predecessor name, Health Purchasing Partners, Inc. ("HPPI"). In 2007, HPPI's parent company formed a new subsidiary, Provista, Inc., which in turn formed a subsidiary named Apexus, Inc. HPPI then assigned the Prime Vendor contract with HRSA to Apexus. For ease in reading this brief, Apexus we will use the name Apexus regardless of whether the brief is describing the acts of HPPI or Apexus. *Id.* at ¶15.

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legal counsel, responded that if vaccines were part of Prime Vendor's value add under the Prime Vendor contract and benefited the public health, then Apexus should include vaccines if the pharmaceutical companies would agree to sell them through the 340B Prime Vendor Program. *Id.* at ¶13. Apexus then began contacting pharmaceutical companies to see if they would be interested in selling vaccines to covered entities through the 340B Program.

When AMB's term as Prime Vendor expired, HRSA solicited a second round of bidding for a new Prime Vendor. *Id.* at ¶15. In the solicitation for the 2004 contract, HRSA included sections for Optional Service and Catalog Items, but it did not define what these products would be. *Id.* It included this new category because AMB, when it submitted its bid for the 1999 Prime Vendor Contract, included an offer of value added products and the covered entities enjoyed the added benefit of those extra products. OPA and HRSA wanted to include them going forward. *Id.*

In its 2004 response to the Solicitation, Apexus included vaccines as part of its offering under Optional Services and Catalog Items. *Id.* Apexus won the bid and in 2004 HRSA selected it as the new Prime Vendor. Because Apexus had included vaccines as part of its bid, and because HRSA had accepted the offer, Apexus had to ensure that vaccines were offered under the 340B Prime Vendor Program. Vaccines were available to covered entities beginning in 2005. *Id.*

In soliciting bids from prime vendor program applicants for the 2009 contract award, HRSA changed the Optional Services and Catalog Items section to the Value Added Products section and stated that Value Added Products would be one of the factors it would consider in awarding the Prime Vendor contract. *Id.* at ¶16. This time, based upon the successful reception from the covered entities regarding the inclusion of vaccines under the 2004 contract, HRSA was more specific about what Value Added Products meant. It specifically stated that it wanted a bidder to offer "[l]ower cost products and services not included in the 340B Program (*e.g.* vaccines, etc.)." *See* HRSA 340B Prime Vendor RFP Response to Solicitation provided by Apexus (the "Proposal") attached as **Exhibit B** and incorporated by reference for all purposes, at pp. 47; 190; 193. In other words, HRSA made the decision specifically to include vaccines within the scope of value added products. It acted within the scope of authority granted to it under enabling legislation and subsequent regulations when making this decision.

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**F. Apexus' Role As Prime Vendor.**

HRSA awarded the 2009 Prime Vendor Contract to Apexus. When determining Apexus' scope of work and its obligations under the 2009 Prime Vendor Contract, the Court should review the Solicitation and the Response because the Prime Vendor Contract between Apexus and HRSA incorporates by reference both the HRSA 340B Prime Vendor Agreement (the "Agreement") and the Proposal. *See* Agreement, attached hereto as **Exhibit A**; Proposal, relevant portions only, attached hereto as **Exhibit B**. The Agreement states that "[i]t is understood and agreed that the 340B Prime Vendor shall in meeting the requirements of this Agreement perform the work in accordance with the proposal to the Health Resources and Services Administration dated April 16, 2009." Agreement at p. 1.

As part of its proposal to the HRSA 2009 Solicitation, Apexus listed twenty-five vaccines for which it could negotiate lower prices for entities involved in the 340B Prime Vendor Program. Proposal, Section B.5, pp. 190-202 (specifically naming several GSK Vaccines). HRSA accepted Apexus' bid and selected it as the Prime Vendor. Under the Agreement, therefore, this Proposal became part of the Agreement, and Apexus was required to include lower prices on the listed vaccines on behalf of all participants in the 340B Program.

Importantly, as the Prime Vendor, Apexus does not manage the 340B Program. The OPA does that. Agreement at p. 1. Rather, Apexus manages the 340B Prime Vendor Program on behalf of HRSA and the OPA through its 5-year contract with HRSA – it is the stand-in on behalf of OPA and HRSA. *Id.*

As the Prime Vendor under the Prime Vendor Program, Apexus has three primary roles. First, it obtains sub-340B pricing for pharmaceuticals on behalf of the covered entities. Second, it establishes distribution networks that improve access to affordable medications. Third, and which is at issue here, it provides other value added products and services, such as discounted vaccines, to the covered entities. *See* generally, *Id.* at pp. 3-6 (providing detailed outline of Apexus' obligations, duties, and responsibilities of the 340B Prime Vendor); *see also* https://www.340bpvp.com/about_us/.

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### G. Plaintiff Claims that Apexus Improperly Included Vaccines in the Prime Vendor Program.

Plaintiff claims that Apexus' compliance with the terms of the Agreement with HRSA violates the Robinson-Patman Act and common law. Plaintiff ignores the fact that HRSA had the authority to structure the 340B Prime Vendor Program and determine what additional materials or products it wanted to include as value added products under the 340B Prime Vendor Program. Plaintiff also ignores the fact that Apexus is the prime vendor on behalf of OPA and HRSA, retained to manage the Prime Vendor Program on their behalf. It must act as directed by HRSA and OPA, and must honor its contract terms.

Apexus' requirement under its Agreement with HRSA to obtain lower prices for vaccines is the basis of Plaintiff's claims against Apexus. Complying with the terms of a government contract should not be the basis for any claim against Apexus by Plaintiff. Accordingly, Apexus has not "conspired to use the Program to agree on reduced prices for vaccines . . . ." Plaintiff's FAC at ¶ 28. Moreover, Apexus has not "improperly used the 340B Program to sell discounted vaccines and they encourage covered entities to resell those vaccines to non-patients." *Id.* at 31. Apexus is merely fulfilling its contract terms. Accordingly, Apexus should not be seen to have engaged in aiding and abetting any unlawful acts. (*Id.* at ¶¶ 63-66).

## V. ARGUMENT AND AUTHORITIES

### A. HRSA and OPA had the Authority to Include Vaccines as Value-Added Products.

#### 1. The Court should defer to the inclusion of vaccines under *Chevron, Inc. v. Natural Resources Defense Corporation.*

Under Supreme Court precedents, an agency is entitled to deference when it fills a gap left by Congress with regard to how to implement a statute or regulation. *United States v. Mead Corporation*, 533 U.S. 218, 227-28, 121 S. Ct. 2164, 2171 (2001) (citing *Chevron, Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 104 S. Ct. 2778 (1984)). In addition, agencies that are charged with applying a statute must make choices on how to implement the tasks assigned to them; such choices may bind courts, and at least are influential on courts. *Id.* "The well-reasoned views

of agencies implementing a statute 'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.'" *Id.* (citing *Bragdon v. Abbott*, 524 U.S. 624, 642, 118 S. Ct. 2196, 2207 (1998)).

HRSA's inclusion of vaccines in the 340B Prime Vendor Program is entitled to *Chevron* deference. *Mead Corp.*, 533 U.S. at 226-27 ("administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority"). Congress provided a broad framework for the 340B Program and the Prime Vendor Program. It offered little specific guidance, however, when it came to the day-to-day operations and scope of the Prime Vendor Program. OPA, HRSA and HHS had to fill the gaps left by Congress. Without HRSA and HHS taking the initiative to act, Congress's mandate for providing low cost supplies and pharmaceuticals to safety net providers would not be realized. *See* **Exhibit C** at ¶¶ 19-21. HRSA, through the OPA, had to create the 340B Prime Vendor Program out of whole cloth. In doing so, it had to determine what actions and contracts were best for the 340B Prime Vendor Program and how to operate the Prime Vendor Program so as to provide for the public health. HRSA was well within its authority to interpret the Value Added Products section broadly to include vaccines. "If a statute speaks clearly to the precise question at issue, courts should give effect to the unambiguously expressed intent of Congress. However, if the statute is silent or ambiguous with respect to the specific issue, courts sustain the agency's interpretation if it is based on a permissible construction of the Act." *Barnhart v. Walton*, 535 U.S. 212, 217-18, 122 S.Ct. 1265, 1269 (2002).

By authorizing Apexus to solicit vaccines from the pharmaceutical companies like GSK, and by including vaccines as a value added product in the Solicitation and the Prime Vendor Program contract, the OPA and HRSA were fulfilling the mandate granted to HHS by Congress to develop and operate the 340B Program and the 340B Prime Vendor Program. By choosing to add vaccines, HRSA also helped define the scope of the Prime Vendor and its mission. Through these decisions,

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HRSA ensured that the OPA and HRSA catered to the public health and ensured that safety net organizations, like SNHD, had access to the best products at the most affordable prices.

**2. HHS and HRSA had the interpretive authority to include vaccines.**

Even if HHS and HRSA did not have implied statutory authority to include vaccines in the Prime Vendor Program as a value added product, the Court should give deference to HRSA's interpretive choice to do so. "[W]hether or not they enjoy any express delegation of authority on a particular question, agencies charged with applying a statute necessarily make all sorts of interpretive choices, and while not all of those choices bind judges to follow them, they certainly may influence courts facing questions the agencies have already answered." *United States v. Mead Corp.*, 533 U.S. 218, 227-28 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161 (1944)). "The well-reasoned views of the agencies implementing a statute constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance, and we have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Id.* (internal marks omitted).

The OPA and HRSA, as the offices charged with managing the 340B Program, were faced with detailed information from covered entities that they wanted vaccines to be available at low cost through the 340B Prime Vendor Program. The need for low cost vaccines would benefit the public health and would increase the value of the 340B Prime Vendor Program. Because the Prime Vendor manages the 340B Prime Vendor Program for OPA and HRSA, they had to rely upon the Prime Vendor, Apexus, to begin the process of including low cost vaccines. And, the only opportunity to include vaccines was to include them as Value Added Products. HRSA's decision to include vaccines in the Prime Vendor Program was based on the purpose and mission of the OPA, HRSA, and the 340B Program. Further, it was consistent with the prior and subsequent actions of the OPA and HRSA. It was a rational solution to a problem faced by the OPA and HRSA in implementing the 340B Prime Vendor Program and meeting the needs of the covered entities. *See Bamonte v. City of Mesa*, 598 F.3d 1217, 1228 (9th Cir. 2010) (citations omitted) (*Skidmore* defense is appropriate when an agency's actions provide a rational and consistent approach to addressing a

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circumstance not covered by regulation or statute). OPA and HRSA made a choice as to how to provide much needed and requested vaccines at a reduced cost to safety net providers and covered entities. That choice should be honored and should not subject Apexus, or any Defendant, to liability.

### B. Apexus Is Entitled to Immunity Because It Is An Instrumentality of the Federal Government.

Apexus manages the Prime Vendor Program on behalf of OPA and HRSA. Because it is performing the management functions of the 340B Prime Vendor Program for OPA and HRSA, Apexus enjoys conduct-based immunity from Plaintiff's claims as an instrumentality of the federal government. That is, because OPA and HRSA could not be liable for the sale of low cost vaccines, neither can Apexus.

It is undisputed that the United States is immune from the antitrust laws. *See U.S. Postal Service v. Flamingo Industries (USA) Ltd*., 540 U.S. 736, 745, 124 S.Ct. 1321, 1327-28 (2004). This immunity includes federal agencies and their officials. *See Name.Space, Inc. v. Network Solutions, Inc*., 202 F.3d 573, 580 (2nd Cir. 2000) (citing *Sea-Land Service, Inc. v. Alaska Railroad*, 659 F.2d 243, 246 (D.C. Cir. 1981)).

"Private parties, to the extent they are acting at the direction or with the consent of federal agencies, also fall outside the pale of the [Sherman Act] where the complained of acts were specifically directed by the federal government." *Id.* at 583. It can also include private entities who act as the instrumentality of a federal agency. *See Name.Space*, 202 F.3d at 581; *Champaign-Urbana News Agency, Inc. v. J. L. Cummins News Co., Inc*., 632 F.2d 680, 692-93 (7th Cir. 1981); *Byers v. Intuit, Inc*., 564 F.Supp.2d 385, 423-24 (E.D. Pa. 2008); *Medical Ass'n of State of Ala. v. Schweiker*, 554 F. Supp. 955, 966 (M.D. Ala. 1983).

In *Name.Space*, the court recognized that private entities acting on behalf of a federal agency may be entitled to "conduct-based instrumentality immunity" from antitrust liability. *Name.Space*, 202 F.3d at 582. In determining whether a private entity is entitled to immunity, courts look at the "nature of the activity challenged rather than the identity of the defendant." *Id.* If

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the conduct at issue was compelled, endorsed, or directed by the federal government via contract or otherwise, immunity applies. *Id.*

The private entity sued in *Name.Space*, NSI, managed the Domain Name System ("DNS") of the Internet through a "Cooperative Agreement" with the National Science Foundation ("NSF"), the federal agency which had previously managed the DNS. *Id.* at 577. The plaintiff was a private firm that assisted customers with the registration of new domain names. At the center of the plaintiff's lawsuit was its request that its Top Level Domain name be added to the seven generic Top Level Domain names currently in existence on the DNS. *Id.* at 579. This change was necessary to insure that the domain names that plaintiff registered for its customers could be located by all Internet users. *Id.* NSI refused to do so, and plaintiff sued NSI under Section 2 of the Sherman Act. *Id.* at 581.

The court affirmed the granting of defendant's summary judgment and the dismissal of plaintiff's claims under Section 2. Applying conduct-based immunity, the appellate court noted that the conduct being challenged was required by, and done pursuant to, NSI's contract with the NSF and the government's policies regarding administration of the DNS. *Id.* at 582. In other words, NSI could not, under the terms of the Cooperative Agreement with NSF, comply with plaintiff's request to add a new generic Top Level Domain name. *Id.* at 583. Thus, NSI had conduct-based instrumentality immunity from plaintiff's Section 2 claims.

The doctrine of conduct-based instrumentality immunity was further explained in *Byers v. Intuit, Inc.*[3] There, the private defendants provided tax preparation and filing services to their customers. 564 F.Supp.2d at 389. These private companies partnered with the IRS to form a consortium of companies (the "Consortium") who would work together to provide free electronic tax preparation and filing service to taxpayers. *Id.* at 390-91. Under the Consortium's agreement with the IRS, this free service would focus exclusively upon those taxpayers earning $54,000 or less. *Id.* at 392. Plaintiffs argued that the Consortium violated Section 1 of the Sherman Act by

[3] Though the case was decided under Rule 12(b)(6) motion, the reasoning behind the finding of conduct-based immunity still applies at the summary judgment stage.

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agreeing to limit the scope of their free electronic filing services to those taxpayers earning less than $54,000. *Id.*

Under Rule 12(b)(6), the district court dismissed plaintiffs' complaint against the private defendants. *Id.* at 428. It held that, while the private defendants were not entitled to status-based immunity, they were entitled to conduct-based immunity. In doing so, the court noted that the Defendants' restriction as to the availability of the free electronic filing services arose directly out of the agreement with the IRS. *Id.* at 426. This was the same conduct that plaintiffs complained of, and therefore, the private defendants were entitled to conduct-based immunity as instrumentalities of the IRS, a federal agency. *Id.*

Apexus has immunity for any type of antitrust claim that Plaintiff might allege related to sale of vaccines by GSK or any other party to SNHD. Apexus has included such vaccines in the 340B Prime Vendor Program under its contract with HRSA. This situation is no different than in *Name.Space* or *Byers*. Apexus cannot be held liable for doing something that a federal agency has contractually obligated it to do. Holding Apexus liable would be the same as trying to hold OPA or HRSA liable for the offering of vaccines. Apexus, therefore, because it is functioning as an instrumentality of the federal government, is entitled to conduct-based immunity from Plaintiff's antitrust claims. *See Name.Space, Inc.,* 202 F.3d at 581; *see generally Air Shuttle Corp. v. Virgin Islands Port. Auth.,* 782 F.Supp. 1070, 1075-76 (D.V.I. 1991) (summary judgment for defendant granted on immunity grounds for awarding an exclusive contract to plaintiff's competitor even though there was no express statutory authority for defendant to issue exclusive leases). Similarly, because Apexus is immune from any antitrust liability, it is also immune from Plaintiff's aiding and abetting claim for violating the Robinson-Patman Act.[4] In addition, because of Apexus' immunity from suit, Plaintiff has no viable cause of action that it could bring against SNHD or GSK. These parties are a covered entity and a contracted supplier respectively, under the 340B Program and they cannot be liable for complying with the terms of their contracts. As a result, Defendants' Motion

[4] Apexus reserves its right to offer any further affirmative defenses to Plaintiff's claims against it, including, but not limited to whether a civil aiding and abetting claim even exists as a matter of law.

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for Summary Judgment should be granted and all claims against all Defendants should be dismissed.[5]

## VI. CONCLUSION

As the prime vendor under the 340B Prime Vendor Program, Apexus is provided conduct-based immunity for the claims in this suit. In addition, OPA's and HRSA's decision to include vaccines in the 340B Prime Vendor Program as Value Added Products was within their authority and is entitled to deference by the Court. Even if immunity does not apply here, the own-use exemption, briefed by the other parties and included herein by reference, applies, meaning that Plaintiff's claims against all Defendants are also barred from suit.

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[5] Contemporaneously with Apexus' filing of this motion, GSK and SNHD have filed their own motions for summary judgment, which includes sections on the "own-use" exception under the Non-profit Institutions Act. Apexus incorporates by reference GSK's and SNHD's arguments, authorities and evidence on that point in support of its motion herein as if fully set forth.

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WHEREFORE, Defendants request this Court grant Defendants' Joint Motion for Summary Judgment, and to award them any further relief, in either law or equity, to which they have shown themselves entitled.

Dated this 22nd day of July, 2014.

Respectfully submitted,

*/s/ Gregory J. Casas*

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**CERTIFICATE OF SERVICE**

Pursuant to Fed. R. Civ. P. 5(b), I hereby certify that on July 22, 2014, service of the foregoing Defendant Apexus, Inc.'s Motion for Summary Judgment was made this date through the United States District Court's CM/ECF electronic filing system.

*/s/ Christina Bonner*

An employee of Greenberg Traurig, LLP

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# EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Administration & Financial Management
Health Resources and Services Administration Division of Procurement Management
HRSA Acquisitions Branch
Room 13A-19, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-5600

# HRSA 340B Prime Vendor Agreement

This Agreement is entered into effective on September 10, 2009, by and between the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services (HHS), and Apexus, a non-profit corporation, duly organized and existing under the laws of Delaware, with its principal office in Irving, Texas (the 340B Prime Vendor). The 340B Prime Vendor shall operate as an independent entity and not as an agent of the Federal Government. It is understood and agreed that the 340B Prime Vendor shall, in meeting the requirements of this Agreement, perform the work in accordance with the proposal to the Health Resources and Services Administration dated April 16, 2009, provided however, that to the extent that any provisions of the articles of this Agreement are in conflict or inconsistent with any provisions of said proposal, the provisions of the articles of this Agreement shall be controlling and shall supersede the provisions of said proposal.

WHEREAS, HRSA, Healthcare Systems Bureau, Office of Pharmacy (OPA), administers the Drug Pricing Program established by Section 340B of the Public Health Service Act (Section 340B);

WHEREAS, HRSA is the HHS agency with the delegated authority to sign the Pharmaceutical Pricing Agreement (PPA) between participating drug manufacturers and HHS, as specified by Section 340B;

WHEREAS, HRSA is responsible for the establishment of a prime vendor program, as mandated by Section 340B(a)(8);

WHEREAS, the 340B Prime Vendor will develop, maintain and coordinate a program capable of price negotiation and distribution of covered outpatient drugs, as defined in Section 340B(b), to member entities;

NOW, THEREFORE, in consideration of the mutual understandings contained in this Agreement, HRSA and the 340B Prime Vendor agree as follows:

## Section I. Definitions

(a) 340B Drug Pricing Program: The outpatient drug discount program for selected safety-net health care providers established by Section 340B.

(b) Covered Entities: Certain HHS grantees, "look alike" Federally Qualified Health Centers, certain disproportionate share hospitals, certain children's hospitals and other entities as described in Section 340B(a)(4).

(c) 340B Prime Vendor Program: The program established pursuant to Section 340B(a)(8) through an agreement between HRSA and one or more private sector organizations to provide prime vendor services to covered entities that choose to participate.

(d) Member Entities: Covered entities that participate in the 340B Prime Vendor Program.

(e) Ceiling Prices: The maximum prices that manufacturers may charge for covered outpatient drugs as determined by the pricing formula in Section 340B.

(f) Dispute: For the purposes of this Agreement, any disagreement between HRSA and the 340B Prime Vendor that arises out of, or is related to, the interpretation, implementation or alleged breach of any provision of this Agreement. The "occurrence date" of a dispute shall mean the date upon which written notice is given by a party to the other party stating the precise nature of the dispute.

**Section II. Responsibilities of HRSA** During the term of this Agreement, HRSA shall have the following responsibilities:

(a) Covered Entities: HRSA, in cooperation with other HHS components, shall maintain a list of covered entities and their sites authorized to purchase covered outpatient drugs at or below 340B prices, as defined in Section 340B(a)(4). This list will be made available to the 340B Prime Vendor as a searchable database.

(b) Information Dissemination: HRSA shall serve as the central source for information concerning the terms and conditions of this Agreement.

(c) Promotion: After selection of the 340B Prime Vendor and signing of this Agreement, HRSA will disseminate information about the 340B Prime Vendor Program to covered entities and encourage their participation throughout the term of the Agreement.

(d) Ceiling Price Confidentiality: HRSA will retain all information regarding the statutory ceiling prices for covered outpatient drugs.

(e) Service Improvement: The HRSA Project Officer will work with the 340B Prime Vendor to continuously improve services for member entities.

(d) The HRSA Project Officer shall be designated by HRSA in an appointment letter sent to the Prime Vendor. HRSA has the unilateral right to appoint and change the designated HRSA Project Officer.

**Section III. Responsibilities of the 340B Prime Vendor** During the term of this Agreement, the 340B Prime Vendor shall, by contract agreement with its wholesale-distributor sub contractors, specify consistent and acceptable levels of service in accordance with standard business practices in these areas:

(a) Distribution Services for all covered outpatient drugs shall be provided to member entities. Other value-added catalog items may be offered to member entities.

(1) Supply of covered outpatient drugs sufficient to their needs shall be available to meet the orders of member entities.

(2) Equipment shall be provided by wholesale-distributor sub contractors, consistent with normal business practices, to each member entity, at no cost to the member entity, and appropriate for electronic order entry and inventory control. Maintenance of such equipment and appropriate training in its use shall be provided. A contact person and telephone number must be provided in the event that additional instruction is necessary.

(3) Fill Rate: Wholesale-distributor sub contractors shall provide next-day delivery for items ordered by the mutually-acceptable, designated order cut off time, with the understanding that items ordered on a Friday shall be delivered on the succeeding Monday, with a fill rate that meets or exceeds current commercial standards in the drug distribution industry. The fill rate shall be individually calculated on a monthly basis for each member entity and a fill rate report will be provided to a member entity upon request.

(4) Delivery is routinely required daily, Monday through Friday, to the delivery point established by the member entity facility's representative. Multiple delivery sites may be needed by member entities. Delivery shall be between the hours of 8:00 AM and 4:00 PM.

(5) Emergency Delivery Service shall be provided by wholesale-distributor sub contractors, twenty-four (24) hours per day, seven (7) days per week. It is required that delivery shall occur within six (6) hours of receipt of emergency order by the wholesale-distributor sub contractor or be deemed a failure. Such failures will be included in fill rate calculations. Emergency delivery of covered drugs required in less than six hours in life threatening situations may be procured from other than the wholesale-distributor sub contractor, and will be exempted from this fill rate standard.

(6) Back-Ordered Item: Member entities shall be notified, as soon as possible, of any manufacturer back ordered or canceled items. This shall free the member entity to seek the product from another source.

(7) Substitution: The wholesale-distributor sub contractors may make brand or generic product substitutions within a therapeutic category only if the member entity concurs. Following notification by the Chief Pharmacist or designated representative of the member entity, the

wholesale-distributor sub contractor shall honor all decisions regarding substitution.

(8) Expiration Dating: Any product bearing an expiration date/shelf life requirement shall have not less than six (6) months remaining upon delivery to the member entity. Products that are manufactured with less than a six (6) months expiration date/shelf life shall be delivered with the best available date.

(9) Returns: The wholesale-distributor sub contractors shall be responsible for accepting returns, in accordance with applicable laws and regulations, for credit, at no charge to the member entity under the following conditions: (1) products shipped in error; (2) products damaged in shipment; (3) products with concealed shipping damages; (4) products with less than six months dating at the time of receipt from the wholesale-distributor sub contractor unless otherwise authorized by the Chief Pharmacist of the member entity or designated representative; (5) recalled products, regardless of level of recall; (6) outdated products that were purchased from the wholesale-distributor sub contractor, are returnable to the manufacturer at a credit rate allowed by the manufacturer and are unopened; and (7) products which are no longer needed if they were purchased from the wholesale-distributor sub contractors, returnable to the manufacturer, and are unopened. Returned products shall be credited to the ordering member entity account.

(10) Reports shall be provided to member entities, upon their request, such as standard industry drug purchasing and utilization reports, as applicable.

(b) Negotiation Services: The 340B Prime Vendor shall directly provide negotiating services in accordance with standard business practices with the purpose of providing all member entities the most advantageous sub-ceiling prices. To facilitate the collection of purchasing volume data for all member covered entities, agreements with wholesale-distributor sub contractors should include provisions protecting the confidentiality of the covered entities' drug purchasing information.

(c) Standards of Performance: The 340B Prime Vendor will propose standards of performance for drug distribution and sub-ceiling price negotiations for generic and brand name drugs that, when accepted by the Government, shall become part of this Agreement. The standards should include, at a minimum, the following elements:

| **Performance Element** | **Standard** |
|---|---|
| Covered entity enrollment | See Section B.3.f (Pages 89-90). |
| Distribution services | See Section B.1.f. (Pages 52-55). |
| Drug price negotiation | See Section B.2.d (Pages 70-76). |

| Performance Element | Standard |
|---|---|
| Value Added Products and Services | See Section B.5 (Pages 190-202). |
| Customer service | See Section B.3.f (Pages 89-90). |
| Data confidentiality | See Section B.2.d (Pages70-71). |
| Reports to HRSA | See Section (h) Reports to HRSA (Pages 14-16). |

(d) Billing: The 340B Prime Vendor agrees that the member entity shall be responsible for all payments for 340B Prime Vendor services. Under no circumstances will HRSA be responsible for such payments.
(e) Covered Entity Contracts: All 340B Prime Vendor contracts with member entities shall contain no terms and conditions that are inconsistent with the terms and conditions of this Agreement, the PPA, and Section 340B or its implementing regulations or guidelines.

(f) Implementation Plan:

The 340B Prime Vendor shall:

(1) Contact all covered entities to inform them of the new Prime Vendor agreement, how to participate in the 340B Prime Vendor Program, and the advantages of participation, within thirty (30) days of the effective date of this Agreement.

(2) Begin delivery of covered outpatient drugs to the member entity at or below the 340B ceiling price, thirty (30) days after a covered entity has joined the 340B Prime Vendor program.

(3) Assure that staff representatives and wholesale-distributor sub contractors are trained in the policies and guidelines of the 340B Drug Pricing Program and the 340B Prime Vendor Program.

(g) Customer Support: The 340B Prime Vendor and its wholesale-distributor sub contractors shall provide or make available toll-free customer service lines. The 340B Prime Vendor's representative shall provide technical assistance to all member entities and shall **promptly** respond to member entity inquiries within 3 business days. Customer support shall be coordinated with the Office of Pharmacy Affairs in order to maximize the value to covered entity clinics and hospitals.

(h) Reports to HRSA: The 340B Prime Vendor shall provide a quarterly report and an annual

summary report to the Project Officer including the following elements: (1) a summary of accomplishments for the previous quarter and program plans for the next quarter, including changes from previous reports; (2) selling prices to member entities for the current quarter, including changes from previous reports; (3) a drug distribution performance report for the previous quarter, including changes from the previous reports that includes fill rates, member entity total dollar sales, and other data, as prescribed by Project Officer; (4) the results of sub-ceiling price negotiations, including changes from the previous reports; and (5) other catalog products and services by selling price and changes from last report. This information shall be provided or made accessible electronically in a mutually agreed upon format with an appropriate security protocol.

(i) Retention of records and auditing: The 340B Prime Vendor shall retain all records pursuant to this agreement, including purchase transactions for member entities and work papers developed for price negotiations, for 3 years after the close of the Prime Vendor Agreement during which the records were created or modified. These records shall be made available for examination by authorized HRSA and other HHS employees, including staff of the Office of the Inspector General, or public accounting contractors designated by that Office.

(j) Compliance with Laws and Regulations: The 340B Prime Vendor represents and warrants that as of the date and for the duration of this Agreement, the 340B Prime Vendor and its wholesale-distributor sub contractors have obtained, and will maintain, all necessary Federal, State and local licenses and permits required to conduct business in all applicable jurisdictions, and will comply with all applicable Federal and State statutes and regulations. The 340B Prime Vendor shall provide timely written notice to HRSA of actions brought against the 340B Prime Vendor by any governmental agency, professional licensing or regulatory agency, or private party.

(k) Manufacturer list of member entities: Upon request, the 340B Prime Vendor shall make available to each participating manufacturer a list of all member entities.

(l) Customer Consultation Group(s): The 340B Prime Vendor shall establish a customer consultation group(s) to assist in the implementation of this Agreement and to provide ongoing consultation. The group(s) will be made up of selected representative member entities. The group(s) should meet at least quarterly, generally by conference call, but at least one of the meetings each year should be in person. The Government Project Officer, or his designee, shall serve as the Government's liaison to the Customer Consultation Group(s).

(m) Service Improvement: The 340B Prime Vendor will work with the HRSA Project Officer to continuously improve services for member entities.

(n) Notification of Manufacturer/Covered Entity Non-Compliance: The 340B Prime Vendor shall notify OPA of any known violations of Section 340B by manufacturers or covered entities.

**Section IV. Transition from Previous 340B Prime Vendor Agreement**

The 340B Prime Vendor under this Agreement shall plan and implement procedures to retain member entities served under the HRSA Prime Vendor Program Agreement, effective September10, 2009 and expiring September 09, 2014. To the greatest extent possible, the transition should be transparent and impose a minimal administrative burden on the member entities and their drug distributors.

The 340B Prime Vendor under this Agreement shall provide a transparent and minimally burdensome transition to a successor organization at the conclusion of this Agreement.

**Section V. Verification and Compliance.**

The Secretary of HHS or his designee may review 340B Prime Vendor internal and external documents as necessary to verify rates and other costs. HHS staff shall have the right to visit the premises of the 340B Prime Vendor and its wholesale-distributor sub contractors during normal business hours and, with at least 24 hours advance notice, inspect relevant documents for the purpose of verifying vendor cost and to ascertain compliance with the terms of this Agreement. The primary purpose of these inspections will be to assure that correct prices are being invoiced to member entities.

**Section VI. Indemnification and Hold Harmless.**

The 340B Prime Vendor shall indemnify, defend and hold HHS harmless from any and all claims, losses, liabilities, costs and expenses (including, without limitation, reasonable attorneys' fees) arising out of the negligence or intentional acts or omissions of 340B Prime Vendor, its employees, agents and wholesale-distributor sub contractors, officers and directors, in carrying out their responsibilities under this Agreement.

**Section VII. Resolution of Disputes.**

(a) Application: The provisions of this section apply only to those disputes between the 340B Prime Vendor and HRSA, and are separate from the informal dispute resolution guidelines published as a final notice in 61 Fed. Reg. 65412, December 12, 1996.

(b) Negotiated Resolution of Disputes: Disputes may be subject to resolution through discussion and negotiation between HRSA and the 340B Prime Vendor. In all cases, the parties shall engage in good faith negotiations with the intent and goal of reaching a resolution of the dispute that will preserve each party's anticipated benefit and respective rights and obligations under this Agreement and avoid Agreement default. Negotiated resolution shall be undertaken by the parties in accordance with the following terms and conditions:

(1) Designation of Persons: Each party shall designate one or more persons who shall be primarily responsible for negotiating resolution of any dispute ("designated persons"). Such designated persons may be selected prospectively by the parties or within 30 days of the occurrence of a dispute.

(2) Negotiation Process: Within ten (10) working days of an occurrence date, the designated persons shall meet or otherwise establish contact and shall make a good faith effort to resolve the dispute to the satisfaction of the parties.

(3) Duration of Negotiations: The parties shall attempt to reach satisfactory resolution of a dispute within thirty (30) days of the occurrence date. This provision shall not preclude the parties from mutually extending the time period another thirty (30) days for such informal resolution of the dispute.

(4) Departmental Appeals Board: If the parties have not reached a satisfactory resolution of the dispute within 90 days of the occurrence date, either party has the right to bring this matter before the Departmental Appeals Board (the "Board"), pursuant to 45 CFR Part 16. Either the 340B Prime Vendor or HRSA must submit a written request to the Board to initiate such a review process. Parties should mail, deliver or fax (202-690-5863) a review request to:

HHS Departmental Appeals Board
Room 637D, Humphrey Building
Washington, DC 20201

The 340B Prime Vendor will send a copy of the request for review to the HRSA project officer at the same time that it requests a Board review. The Board will advise the 340B Prime Vendor of the next steps in the process.

**Section VIII. Terms**

The term of this Agreement shall commence on the effective date of this Agreement and shall remain in effect for two (2) years unless otherwise terminated as set forth in Section IX. The Government, however, reserves the right to exercise three (3) one-year options to extend this Agreement. The options may be exercised upon notification from HRSA to the 340B Prime Vendor not less than sixty (60) days prior to expiration of the current Agreement or any of the options.

**Section IX. Termination**

(a) Grounds for Termination: This Agreement may be terminated by:

(1) Mutual agreement of the parties at any time, without compensation or other additional payment;

(2) HRSA, if the 340B Prime Vendor has materially breached or failed to perform any of its obligations under this Agreement, which breach or failure continues uncorrected for a period of 30 days after written notice of breach or failure has been sent; or

(3) HRSA upon insolvency, bankruptcy, or other extraordinary business or financial situations that may render the 340B Prime Vendor unable to perform its obligations under this Agreement.

(b) HRSA may terminate the Agreement, immediately, for the convenience of the Government.

**Section X. Miscellaneous**

(a) Federal Funds: Nothing in this Agreement shall be deemed to be a commitment or obligation of Federal funds.

(b) Compliance with Federal Law: To the extent any term of this Agreement is inconsistent with one or more provisions of any applicable Federal law or regulation, the applicable provision of Federal law or the regulation shall govern. This Agreement shall be deemed to be governed by Federal common law, where appropriate.

(c) Assignment and Sub contracting: Except for sub contracts specifically permitted by this Agreement, the 340B Prime Vendor may not assign this Agreement to another organization, nor any of its respective rights and responsibilities under this Agreement, without the prior, written consent of HRSA.

(d) Amendment: Changes to substantive terms and conditions of this Agreement may be effected only by a written bilateral modification to the Agreement signed by both parties. Changes that are merely administrative and do not affect substantive terms and conditions to the Agreement may be made on a unilateral basis by HRSA. HRSA shall provide written notification of said changes to the 340B Prime Vendor.

(e) Non-Assumption of Liabilities: Neither HRSA nor the 340B Prime Vendor shall be liable for any of the prior, existing, or future obligations, liabilities or debts of the other party.

(f) Independent Contractors: Nothing in this Agreement is intended to create an employment or agency relationship between the parties. Neither party shall be deemed to be an employee or agent of the other.

(g) Notice: Any written notice or communication required to be given by this Agreement shall be deemed given when either personally delivered to the person designated below, or when mailed by private delivery service or United States registered or certified mail, postage prepaid to the following:

HRSA:

Health Resources and Services Administration
Division of Grants and Procurement Management
5600 Fishers Lane, Room 13A-19
Rockville, MD 20857
Attention: Francis R. Murphy, Contracting Officer

340B Prime Vendor:

Apexus, Inc.
125 East John Carpenter Freeway, 14th Floor
Irving, Texas 75062
Attention: Mr. Christopher A. Hatwig

Notices sent by mail shall be effective on the earlier date of the date actually received at the address listed above or on the date of receipt as indicated on a receipt verification provided by the delivery service of the Postal Service.

(h) Waiver: The waiver or failure of either party to enforce the terms of this Agreement shall not constitute a waiver of that party's rights under this Agreement with respect to any other violation.

(i) Force Majeure: Neither party shall be considered to have failed in the performance of this Agreement if such failure arises out of causes beyond the control and without the fault or negligence of the party failing to perform. The 340B Prime Vendor shall not be excused from strict compliance with this Agreement due to errors, omissions or failures by its independent contractors or sub contractors.

(j) Severability: Each provision of this Agreement is intended to be severable. If any provision is waived, deemed illegal or invalid for any reason, such waiver, illegality or invalidity shall not affect the validity and enforceability of the remainder of this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed.

APEXUS, INC.
(THE 340B PRIME VENDOR)

By: Christopher A Hatwig

Title: Vice President

Date: 06/05/09

HEALTH RESOURCES AND SERVICES ADMINISTRATION

By _____
Francis R. Murphy

Title: HRSA Contracting Officer

Date 6/16/09

**Barnes,John C.**

**From:** Barnes,John C.
**Sent:** Friday, June 19, 2009 4:02 PM
**To:** Barnes,John C.
**Subject:** FW: HIGPA Wednesday eNews

DEAR APEXUS SUPPLIERS – FYI -

PRESS RELEASE

Jun 16, 2009, 10:40 a.m. EST

# Apexus Wins U.S. Health Resources and Services Administration 340B Prime Vendor Contract


IRVING, Texas, Jun 16, 2009 (BUSINESS WIRE) -- Apexus, announced today that is has been awarded the 340B Prime Vendor Contract by the U.S. Health Resources and Services Administration (HRSA). The five-year contract is effective September 10, 2009. Apexus has managed the Prime Vendor Program since June 2003 and was selected over two other companies in a recent competition.

Apexus, a non-profit subsidiary of Provista Inc., currently represents over 9,000 of the government's eligible 340B facilities (including hospitals, community health centers and family planning clinics) which collectively represent 90 percent of reported purchases in the 340B Drug Pricing Program. These organizations spend more than $4.5 million on outpatient drugs within the 340B Drug Discount Program annually. All eligible covered entities in the U.S. are eligible to join HRSA's 340B Prime Vendor Program on a voluntary basis to access additional discounts on pharmacy products and services.

"We are thrilled to be awarded the HRSA's Prime Vendor contract. The program offers a significant opportunity for qualifying hospitals and other providers to save on outpatient drugs and supplies," said Chris Hatwig, vice president, Prime Vendor Program, for Apexus. "Through the program, qualifying hospitals and all of HRSA's smaller grantees can shave between two percent and 35 percent from the 340B ceiling prices on selected products. This is especially important considering the rising number of uninsured patients served by these institutions."

Section 340B of the Public Health Service Act was established as part of the Veterans Health Care Act. This federal legislation provides discounts on outpatient drug purchases for eligible covered entities, which include public hospitals, community health centers, clinics and other safety-net providers that serve a disproportionate share of low

income and uninsured patients. Through the programs, these entities can purchase outpatient pharmaceuticals at discounted pricing, thereby expanding access to care to low-income and vulnerable segments of the population.

As the Prime Vendor Program contract holder, Apexus is responsible for negotiating pharmaceutical pricing below the 340B ceiling price, and for improving access to affordable medications by establishing a distribution network for pharmaceuticals to covered entities.

Health care providers that wish to join the Prime Vendor Program can visit www.340bpvp.com or call 888-340-2747.

About Apexus

Founded in 2007, Apexus Inc., a nonprofit corporation, is the HRSA's Office of Pharmacy Affairs awarded contractor to serve as the prime vendor for the 340B Program. Based in Irving, Texas, the prime vendor's role is to secure sub-ceiling discounts on outpatient drug purchases and discounts on other pharmacy related products and services for participating public hospitals, community health centers, and other safety-net health care providers electing to join the program. For more information on Apexus, go to www.340bpvp.com.

SOURCE: Apexus Inc.

Apexus Inc.

Kathryn Goldstein, 972-581-5529

Best Regards,
John

John C. Barnes, CPM
Portfolio Executive
340B Prime Vendor Program/ Apexus Inc.
125 East John Carpenter Fwy. 14th Floor
Irving, TX 75062
Ph: 972-910-6634
Fx: 972-910-6699
jbarnes@340bpvp.com
www.340bpvp.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Administration & Financial Management
Health Resources and Services Administration Division of Procurement Management
HRSA Acquisitions Branch
Room 13A-19, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-5600

August 14, 2009

Mr. Christopher A. Hatwig, M.S., R.Ph, FASHP
Senior Director
340B Prime Vendor Program/Apexus, Inc.
125 East John Carpenter Freeway
Irving, Texas 75062-2324

Ref: HRSA-HSB-PVA-09 "HRSA Prime Vendor Agreement"
Amendment One (1).

Dear Mr. Hatwig:

The purpose of this amendment to the above referenced agreement, "HRSA Prime Vendor Agreement" is to add the following:

In Section III, "Responsibilities of the 340B Prime Vendor," the following responsibility is added:

(11) Other Value Added Services and Products Other value added services and products for safety net providers (both participating and non-participating) with the Prime Vendor Program that includes such services as logistical support for meetings in support of the 340B Program and the Patient safety/Pharmacy Collaborative that may include travel, lodging, per diem, registration and professional recognition (excluding Federal Employees) when applicable.

All other terms and conditions remain unchanged by virtue of this amendment. The Period of Performance remains September 10, 2009 through September 9, 2011.

Any questions regarding this amendment should be directed to the contract specialist, Daniel Matusiewicz, dmatusiewicz@hrsa.gov at 301.443.4703. Please sign this amendment and return a copy at your earliest convenience.

Vendor Agreement

Reference: HRSA-HSB-PVA-09 "HRSA Prime

Sincerely,

Francis R. Murphy
Contracting Officer

Date 8/31/09

Acceptance:

Christopher Hatwig
Senior Director

Date 8/28/09

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Administration & Financial Management
Health Resources and Services Administration Division of Procurement Management
HRSA Acquisitions Branch
Room 13A-19, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-5600

March 18 2010

Mr. Christopher A. Hatwig, M.S., R.Ph, FASHP
Senior Director
340b Prime Vendor Program/Apexus, Inc.
125 East John Carpenter Freeway
Irving, Texas 75062-2324

Ref: HRSA-HSB-PVA-09 "HRSA Prime Vendor Agreement"

Dear Mr. Hatwig:

The purpose of this letter is to notify you of a change in the Government Project Officer for the above referenced agreement. As per "Section II. Responsibilities of HRSA, paragraph (d) The HRSA Project Officer", the following appointment and change have been made:

Co-Project Officer
Krista Pedley
Room 10C-03 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Office 301.443.5294
Fax 301 594.4982
KPedley@hrsa.gov

Except as noted above all other terms and conditions of this Agreement remain unchanged and in full force. Any inquires regarding this notice should be directed to Daniel Matusiewicz, contract specialist at 301.443.4703 or dmatusiewicz@hrsa.gov.

Sincerely,

Francis R. Murphy
Contracting Officer
HRSA

cc: Jimmy Mitchell

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Office of Operations
Office of Acquisition Management and Policy
5600 Fishers Lane
Rockville, MD 20857-5600

March 23, 2011

Apexus, Inc.
Attn. Mr. Christopher A. Hatwig,
M.S. R.Ph., FASHP, Senior Director
340b Prime Vendor Program
125 East John Carpenter Freeway,
Irving, Texas 75062-2324

Ref: HRSA-HSB-PVA-09-HRSA Prime Vendor Agreement(Agreement)

Dear Mr. Hatwig,

The purpose of this letter is to acknowledge receipt and to accept the Apexus standard practice to keep agreements, amendments, extensions and correspondences relating to the HRSA-HSB-PVA-09-Prime Vendor Agreement six(6)years instead of the three(3) year minimum requirement in the subject agreement.

This Apexus, Inc. retention practice surpasses the minimum requirement in the Agreement is acceptable to the HRSA. Please find the Contracting Officers signature on the Apexus, Inc. letter dated February 22, 2011.

Except as noted above, all the other terms and conditions of this Agreement remain unchanged and in full force. Any inquiries regarding this notice shall be directed to Mr. Mario Checchia via email, mchecchia@hrsa.gov or by telephone 301.443.3556.

Sincerely,

Francis R. Murphy
Contracting Officer
HRSA

cc. Krista Pedley

FM

Apexus.

February 22, 2011

Health Resources Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane
Parklawn Bldg, Room 13A-19
Rockville, MD 20857

Attn: Francis Murphy, HRSA - Contracting Office

Re: Record Retention Requirements Relating to the Prime Vendor Agreement between Apexus, Inc. and the Health Resources Services Administration, dated September 10, 2009 (the "Agreement")

Dear Mr. Murphy:

Apexus has recently adopted a new Records Management Policy designed to ensure that Apexus appropriately retains and disposes of all records used in our business. Apexus is committed to ensuring that we honor all of our legal and contractual obligations, including those contained in the Agreement. To that end, I am writing to confirm certain of Apexus' key record retention requirements and ensure that they are acceptable to the Health Resources Services Administration ("HRSA").

The Agreement references a 3 year retention period for records created pursuant to the Agreement. Apexus' standard practice is to keep agreements, amendments, extensions and correspondence relating thereto for 6 years after the expiration or termination of the agreement in question. Data relating to product sales and administrative fees is retained for 10 years after the expiration or termination of the agreement in question. Of course, all data will be retained for longer periods of time in the event of litigation or other circumstances requiring a litigation hold.

We are hopeful that these key retention practices are acceptable to HRSA. If so, I would appreciate it if you would return a signed copy of this letter signifying your approval. If not, I would appreciate it if you could direct us to the relevant statute, regulation or policy governing the retention of these records so that we can be sure to meet HRSA's expectations. Please feel free to contact me if you have questions or would like to arrange a meeting with our respective legal counsel.

Sincerely,

Christopher A. Hatwig, M.S., R.Ph., FASHP
Vice President
Apexus/340B Prime Vendor Program

RECEIVED

125 E. John Carpenter Fwy. • Irving, TX 75062 • Ph: 888.340.2787 •

AGREED TO:

Health Resources and Services Administration

By: [signature]

Name: Francis R. Murphy

Title: Contracting Officer Health Resources and Services Administration

Date: 3/23/11

cc: Cmdr Krista Pedley

File: HRSA: Contracting Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Office of Operations
Office of Acquisition Management and Policy
5600 Fishers Lane
Rockville, MD 20857-5600

September 2, 2011

Apexus, Inc.
Attn. Mr. Christopher A. Hatwig,
M.S. R.Ph., FASHP, Senior Director
340b Prime Vendor Program
125 East John Carpenter Freeway,
Irving, Texas 75062-2324

Ref: HRSA-HSB-PVA-09-HRSA Prime Vendor Agreement(Agreement)

Dear Mr. Hatwig,

The purpose of this letter is to notify you that the Government hereby exercises Option Year One(1) of the HRSA 340B Prime Vendor Agreement. In accordance with the Agreement, Section VIII, Terms, the Agreement is extended through the exercise of Option Year One(1) by one year (September 10, 2011 through September 9, 2012). As a result of this action, the new term of the agreement is from September 10, 2009 through September 9, 2012.

Except as noted above, all the other terms and conditions of this Agreement remain unchanged and in full force. Any inquiries regarding this notice shall be directed to Mr. Mario Checchia via email, mchecchia@hrsa.gov or by telephone 301.443.3556.

Sincerely,

Francis R. Murphy
Contracting Officer
HRSA

cc. Krista Pedley

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Office of Operations
Office of Acquisition Management and Policy
5600 Fishers Lane, Pklwn. Rm 13A43
Rockville, MD 20857-5600

September 4, 2012

Apexus, Inc.
Attn. Mr. Christopher A. Hatwig,
M.S. R.Ph., FASHP, Senior Director
340b Prime Vendor Program
125 East John Carpenter Freeway,
Irving, Texas 75062-2324

Ref: HRSA-HSB-PVA-09-HRSA Prime Vendor Agreement(Agreement)

Dear Mr. Hatwig,

The purpose of this letter is to notify you that the Government hereby exercises Option Year Two(2) of the HRSA 340B Prime Vendor Agreement. In accordance with the Agreement, Section VIII, Terms, the Agreement is extended through the exercise of Option Year Two(2) by one year (September 10, 2012 through September 9, 2013). As a result of this action, the new term of the agreement is from September 10, 2009 through September 9, 2013.

Except as noted above, all the other terms and conditions of this Agreement remain unchanged and in full force. Any inquiries regarding this notice shall be directed to Mr. Mario Checchia via email, mchecchia@hrsa.gov or by telephone 301.443.3556.

Sincerely,

Francis R. Murphy
Contracting Officer
HRSA

cc. Krista Pedley

# EXHIBIT B

Apexus

340B Prime Vendor PROGRAM

# HRSA 340B PRIME VENDOR RFP RESPONSE

## Solicitation No.
## HRSA-HSB-PVA-09

## Original Version

Apexus Inc.
Chris Hatwig
Vice President
Phone: (972) 910-6646
Fax: (972) 910-6699

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demonstrated by providing a curriculum vitac/resume of the offeror's key personnel

b. Experience in providing prime vendor (i.e., negotiation and distribution) services. Organizational structure, mechanism to service geographically dispersed entities, mechanism to effectively negotiate prices with large numbers of manufacturers, and adequate physical plants and equipment must be described in adequate detail for assessment.

c. In the case of a proposal that involves the participation two or more organizations, a delineation of the relationship among the participants, including the authority of the lead organization to manage 340B Prime Vendor operations as a whole. If the proposal envisions the participation of other organizations in the future, a statement of how they will be accepted and function within the overall concept.

d. The proposed program implementation methodology in sufficient detail to evaluate offeror's ability to make the transition to full scale operations consistent with the Agreement's effective date.

**5. Value of Optional Products and Services 10%**

a. Lower Cost products and services not included in the 340B Program (e.g. vaccines, etc)
b. Share backs, rebates or other reductions of covered entity cost
c. Other actions or services that bring additional value to entities and the Government.

B. TECHNICAL EVALUATION CRITERIA

| Element | Weight |
|---|---|
| 5. Value of Optional Products and Services | 10% |

a. Lower Cost products and services not included in the 340B Program (e.g. vaccines, etc)

b. Share backs, rebates or other reductions of covered entity cost

c. Other actions or services that bring additional value to entities and the Government.

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## B.5.a.
## Lower Cost Products and Services Not Included in the 340B Program:

As HRSA's contracted 340B PVP, Apexus has added and will continue to add numerous value-oriented, non-covered pharmacy related products and services for 340B Prime Vendor participants. Each of the products and services affords the covered entities the ability to improve patient care by deriving added value within their pharmacy's or broader clinic's operations.

The menu of value added products and services available through the Prime Vendor have served to attract additional covered entities to join the PVP. Over the last five years, the list has grown to be quite extensive in both quantity and scope.

Figure 116: The following is a table listing all of the value added products and services currently available.

| 340B Split-Billing Software | |
|---|---|
| Supplier Name | Agreement Description |
| AutoMed ABC Technology Group / Choice System | 340B Split Billing / Virtual Inventory Replenishment Software |
| eAudit Solutions | 340B Split Billing / Virtual Inventory Replenishment Software |
| Talyst | 340B Split Billing / Virtual Inventory Replenishment Software |
| [illegible] | |
| Supplier Name | Agreement Description |
| Bayer Diagnostics | Diabetic supplies; Meters & Strips |
| Can-Am Care, LLC | Insulin and Tuberculosis Syringes |
| REDACTED | REDACTED |
| Abbott Labs (Pending) | Diabetic supplies; Meters & Strips |
| **Diagnostic Tests and Supplies** | |
| Supplier Name | Agreement Description |

| | |
|---|---|
| REDACTED | REDACTED |
| REDACTED | REDACTED |
| Okamoto USA, Inc. | Condoms and disposable Heat Pads |
| Trinity Biotech | Rapid HIV Test Kits |
| **Health Management/Clinical Outcome Software** | |
| Supplier Name | Agreement Description |
| REDACTED | REDACTED |
| **Interactive Voice Response Systems (IVR)** | |
| Supplier Name | Agreement Description |
| ScriptPro® | Pharmacy Management System / Point-of-Sale / Interactive Voice Response (IVR) |
| REDACTED | REDACTED |
| **Outpatient Pharmacy Management Systems (Software)** | |
| Supplier Name | Agreement Description |
| AutoMed - Telepharmacy Solutions ABC Technology Group | Telepharmacy solutions; Automated Drug Dispensing System (ADDS) |
| ScriptPro® | Pharmacy Management System / Point-of-Sale / SP Central Workflow System |
| QS-1 | Pharmacy Management System / Point-of-Sale |
| **Overcharge Recovery Services** | |
| Supplier Name | Agreement Description |
| eAudit Solutions | Real-Time Web Based Price Audit Software |
| S/T Health Group Consulting, Inc | Retrospective Price Auditing Services |
| **Patient Assistance Programs - Indigent Drug Recovery** | |
| Supplier Name | Agreement Description |
| DrugAssistant | Patient Assistance Program Software – Web based system |
| M&D Cares | Patient Assistance Program Software – Lease/Outsource |
| MedData Services | Patient Assistance Program – Web based Software |
| **Patient Safety** | |
| Supplier Name | Agreement Description |
| REDACTED | REDACTED |
| REDACTED | REDACTED |
| Standard Register | Medication Reconciliation – Web based Software |

| | |
|---|---|
| Standard Register | Tamper-Resistant Prescription Pads, Labels and Equipment |
| | |
| **Pharmacy Automation Systems (Hardware/Robotics)** | |
| Supplier Name | Agreement Description |
| AutoMed ABC Technology Group | Scalable Automation Efficiency Equipment |
| REDACTED | REDACTED |
| Kirby Lester | Pill Counting Technology Solutions |
| ScriptPro® | Robotic Dispensing Systems; Workflow Systems |
| | |
| **Pharmacy Benefits Manager (PBM)** | |
| Supplier Name | Agreement Description |
| REDACTED | REDACTED |
| REDACTED | REDACTED |
| Global Pharmaceutical Solutions | Claims & Clinical Mgt., Customized Reporting, Rebate Contracting, Plan Design, Pharmacy Networks, Specialty Pharmacy Mgt. |
| REDACTED | REDACTED |
| **Pharmacy Supplies** | |
| Supplier Name | Agreement Description |
| Berry Plastics / Kerr Group | Prescription Vials |
| REDACTED | REDACTED |
| Total Pharmacy Supply | Apothecary Supplies |
| Tri-State Distribution | Prescription vials, Labels, & Imaging |
| **Prepackaging Service** | |
| Supplier Name | Agreement Description |
| Dispensing Solutions Inc. | Prepackaged Unit-of-Use 340B Products |
| **Reverse Distribution Solutions** | |
| Supplier Name | Agreement Description |
| EXP Pharmaceutical Services Corporation | Pharmaceutical returns and waste disposal |
| **Telepharmacy Solutions** | |
| Supplier Name | Agreement Description |

| | |
|---|---|
| AutoMed - Telepharmacy Solutions ABC Technology Group | Telepharmacy solutions |
| ScriptPro® | Telepharmacy solutions |
| **Vaccines** | |
| Supplier Name | Agreement Description |
| REDACTED | REDACTED |
| GSK Vaccines | Boostrix Vaccine syringe |
| GSK Vaccines | Boostrix Vaccine vial |
| GSK Vaccines | Engerix-B 10 mcg/0.5 ml pedi syringe |
| GSK Vaccines | Engerix-B 10 mcg/0.5 ml syringe |
| GSK Vaccines | Engerix-B 20 mcg/ml syringe |
| GSK Vaccines | Engerix-B 20 mcg/ml vial |
| GSK Vaccines | Fluarix 2008-09 syringe |
| GSK Vaccines | Flulaval 2008-09 vial |
| GSK Vaccines | Havrix 1,440 Units/ml syringe |
| GSK Vaccines | Havrix 1,440 Units/ml vial |
| GSK Vaccines | Havrix 720 Unit/0.5 ml syringe |
| GSK Vaccines | Havrix 720 Units/0.5 ml vial |
| GSK Vaccines | Infanrix PF Vaccine syringe |
| GSK Vaccines | Infanrix Vaccine vial |
| GSK Vaccines | Kinrix Tip-Lok syringe |
| GSK Vaccines | Kinrix vial |
| GSK Vaccines | Pediarix 0.5 ml syringe |
| GSK Vaccines | Pediarix 0.5 ml vial |
| GSK Vaccines | Rotarix Suspension |
| GSK Vaccines | Twinrix Vaccine syringe |
| GSK Vaccines | Twinrix Vaccine vial |
| Novartis Vaccines | Fluvirin 2007-08 vial |
| Novartis Vaccines | Rabavert Rabies Vaccine Kit |
| Sanofi Pasteur (pending) | Adacel Vaccine |

Current product categories include the following: (All products and services in these categories are priced below comparable rates that would be available to the entities. Many times the pricing is the same as FSS or VA pricing.)

*Inventory Management/340B Split-Billing Software* – This software enables covered entities to optimize the use of the 340B program within their patient care environment by automating many of the ordering, auditing and reporting processes. The software is crucial for mixed use settings to be able to manage 340B inventory in a virtual manner.

[redacted]

*Diagnostic Tests and Supplies (Non –Covered Product)* – The healthcare industry has seen a change in testing methodology from traditional diagnostic testing to diagnostic test kits for home and professional use. Apexus offers over-the-counter test kits for home use, and professional test kits for Point-of-Care use in hospitals and/or clinical sites reduce health care costs, without compromising quality. These diagnostic test kits are FDA and CLIA registered and offer 98-99% test accuracy and are safe and easy to use. Through a wide range of tests such as pregnancy, ovulation, blood Glucose, cholesterol, menopause, ulcer Bacteria, colorectal screening, multiple drug detection, alcohol blood levels, blood pressure monitor, urinary tract infection, rapid HIV test kits, condoms, and more, PVP participants have realized an average annual savings of approximately $340,000.

*Health Management / Clinical Outcome Software* – Abacus has been awarded over $8 million in federal funding from Small Business Innovation Research grants from multiple divisions of the federal government including the *National Institutes on Health* and the *Agency for Healthcare Research and Quality*. Those grants primarily funded the research and development of evidence-based, consumer decision-support eHealth tools that are effective in improving health outcomes.

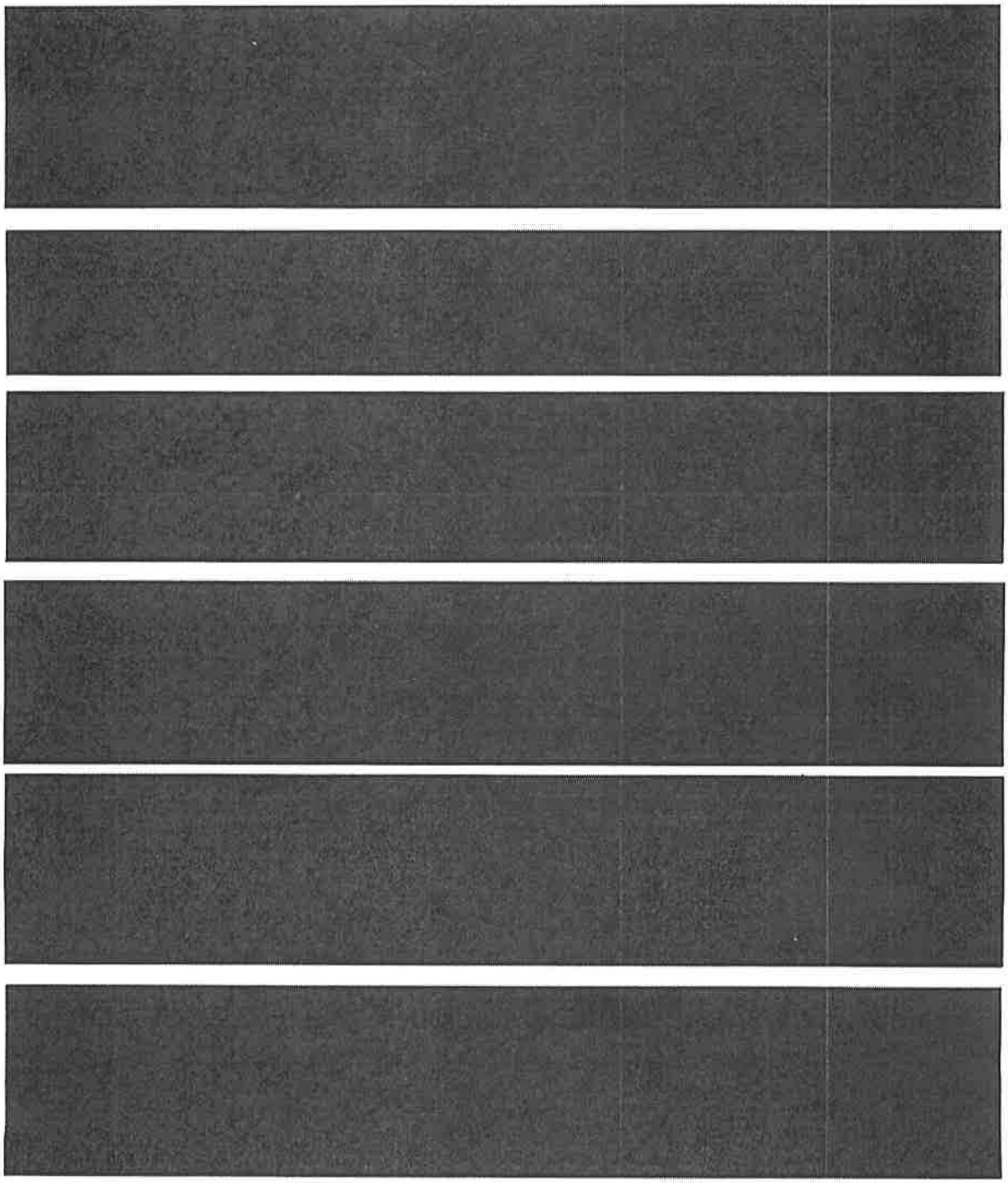
*Interactive Voice Response Systems* – IVR systems provides convenience to patients and relief for the pharmacy staff. Using the key pad on their telephone, callers can place prescription refill orders - anytime day or night. The system verifies the prescription number and refill availability. The caller hears a friendly confirmation that their order has been submitted. For large outpatient pharmacies, these systems provide a level of automation and efficiency that is critical.

[redacted]

*Overcharge Recovery Services* – Auditing services are available for participants seeking to recover overcharges related to 340B program pricing. The 340B price file is the most complex and dynamic price file in the market place. As a result distributors often have to make pricing corrections. These services are integrated with our Authorized Distributor systems and automatically feed daily invoices for analysis without the need for customer involvement. A retrospective offering allows participants to audit pricing from past periods.

*Patient Assistance Programs – Indigent Drug Recovery* – These services enable providers to register and qualify patients for pharmaceutical company's patient assistance programs to receive free drugs by meeting each company's financial eligibility requirements. This is a service that aligns well with the 340B Prime Vendor Program since our participants treat the majority of indigent and working poor that would be eligible for such programs. The Prime Vendor Program currently has

agreements with three vendors that will enable participants the option of purchasing software, accessing an internet-based service, or implementing a turnkey operation that may include the vendor placing staff on site.

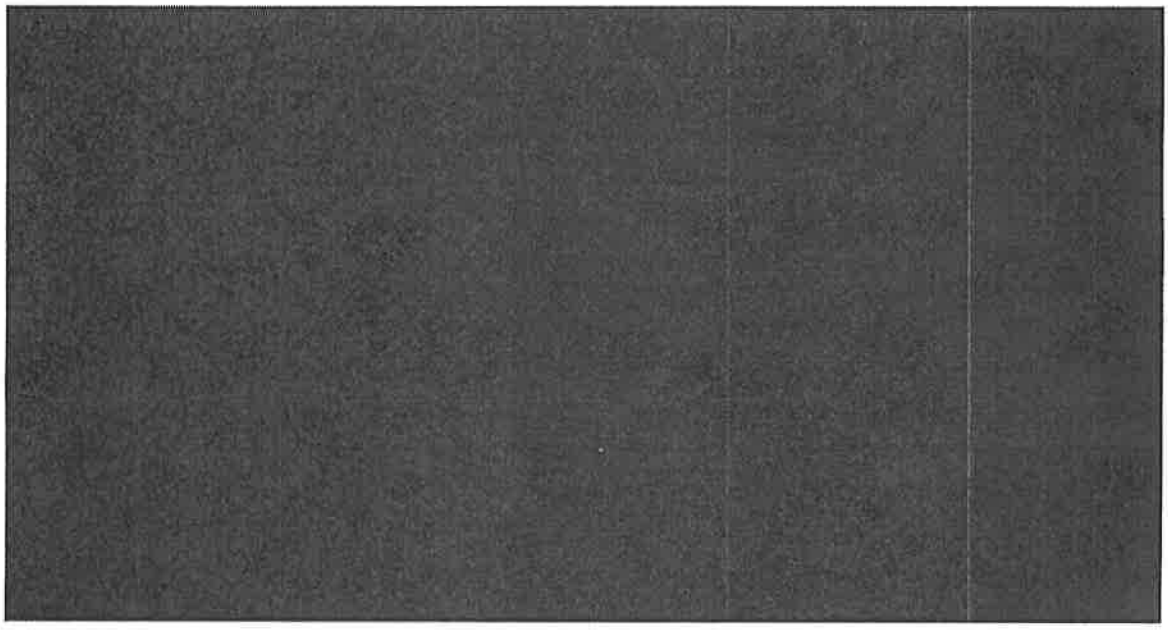


*Reverse Distribution Services* – Processing of pharmaceutical returns via a third party.

Services include:

- On-site returns processing
- Off-site returns processing
- Processing returns to the manufacturer including Schedule 2-5 drugs
- Tracking credits and reconciliation
- Regulatory compliance: FDA, DEA, OSHA, local laws
- Hazardous waste disposal

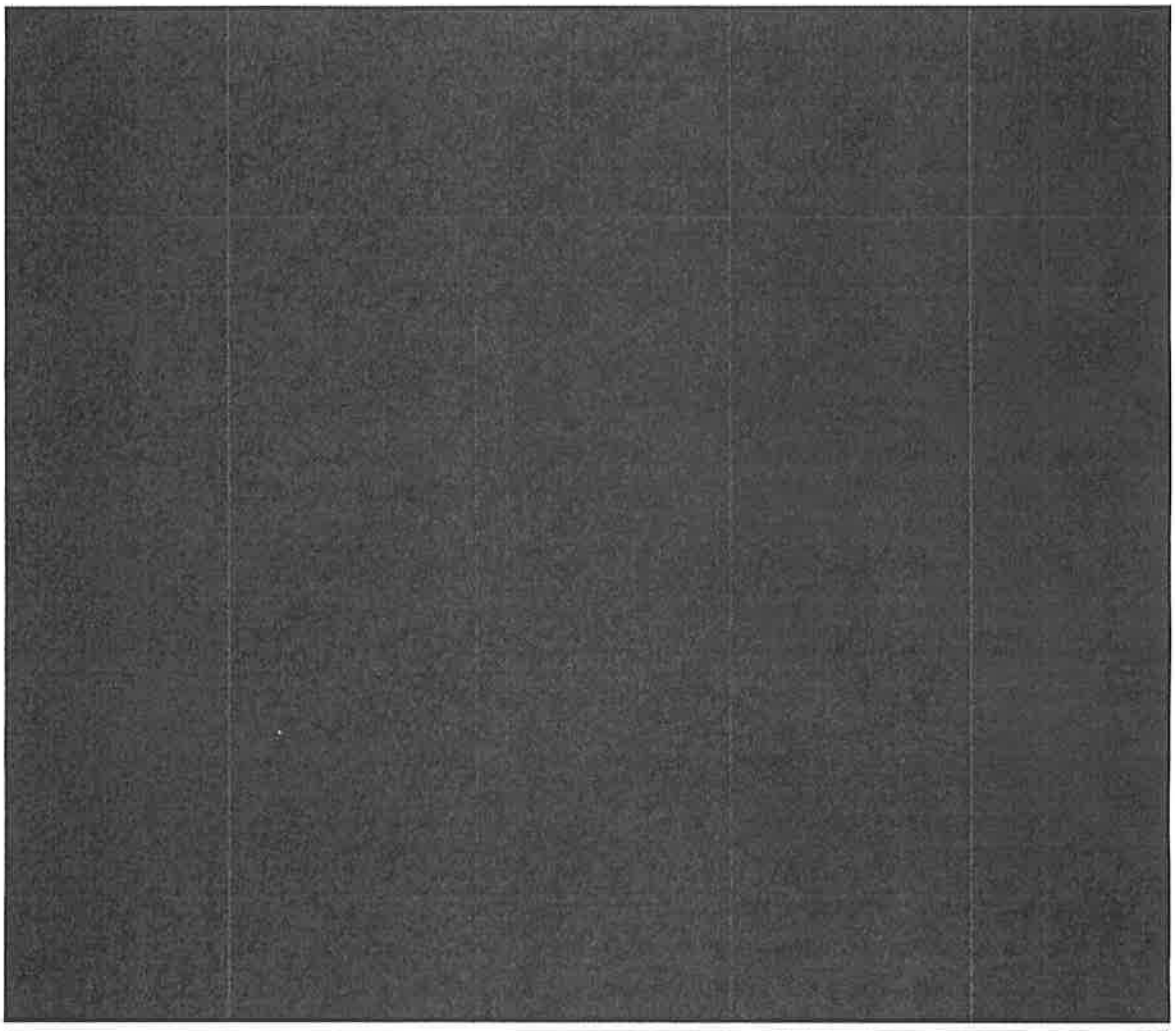
*Telepharmacy Solutions* – Telepharmacy systems help pharmacists reach new patients and new markets, improve patient care, and enhance medication safety all while controlling prescription costs. Telepharmacy systems integrate remote or local pharmacist-controlled dispensing system cabinetry and software, pharmacy software and televideo technology into one seamless system. Telepharmacy is bringing real-time medication dispensing and pharmacist counseling directly to the point-of-care regardless of how remote the patient might be.



B.5.b.

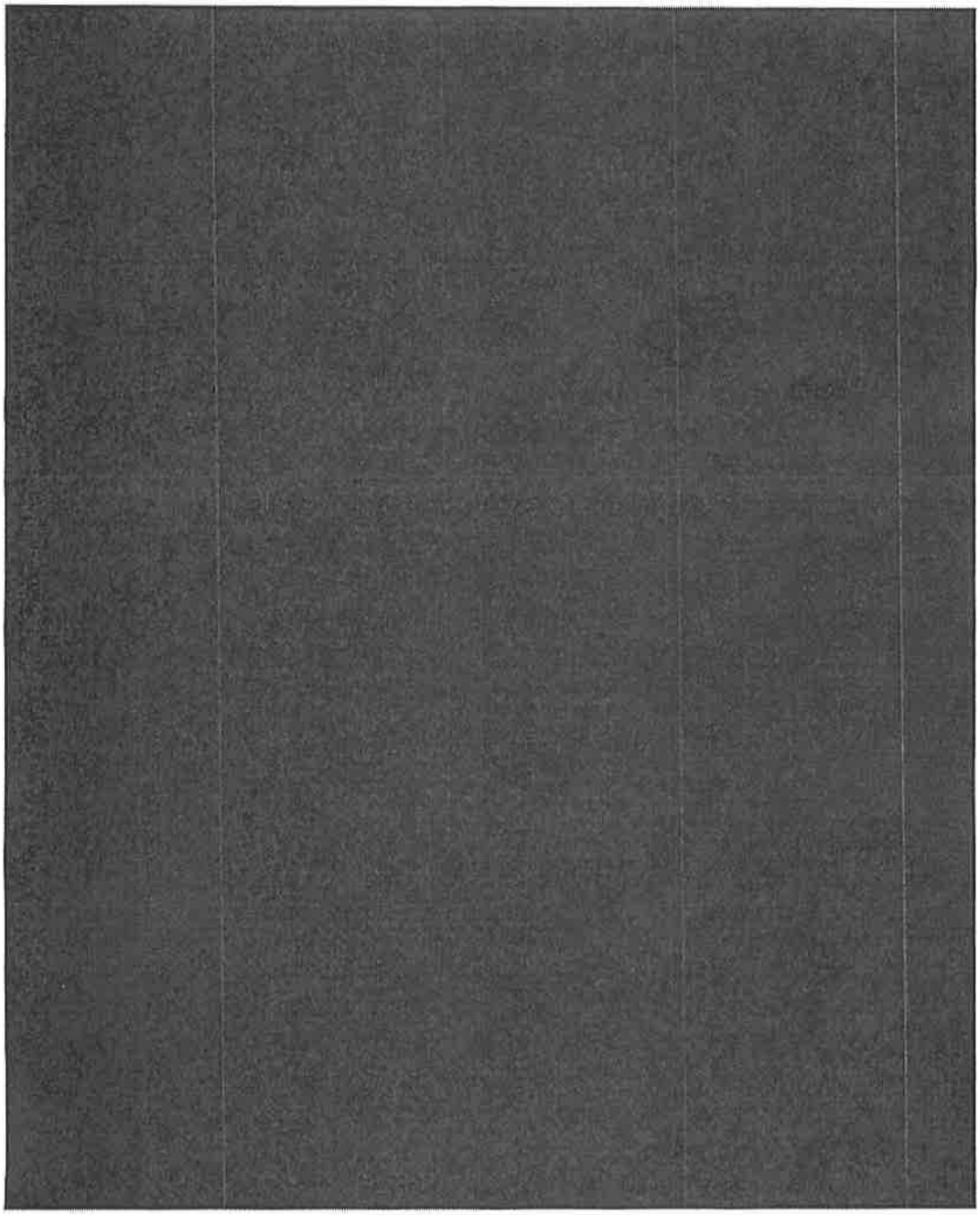
## Sharebacks, rebates, or other reductions of covered entity cost:

In June of 2007, Provista transitioned management of the 340B Prime Vendor Program over to Apexus Inc., a taxable nonprofit corporation. This was an important decision in that the 340B Prime Vendor represents healthcare for a large percentage of indigent care in this country and a non-profit status is better aligned with this mission. As a result, the Apexus Board of Directors determined that a participant shareback program would be the most efficient method for sharing excess program revenue. A shareback program is another way that Apexus will continue to bring additional value to its participants. The first shareback, which was issued via wholesaler credit at the end of 2008, totaled over two million dollars. Over 1,000 PVP participants received a shareback distribution in the form of an electronic credit applied to their respective 340B pharmacy wholesaler accounts. The Apexus Board has recommended an additional shareback of $2 million in 2009. The following outlines the procedure for conducting the shareback.



Accountability

Finance and outside auditors will audit the share-back methodology and review the distribution and calculations for consistency and accuracy.



B.5.c.

## Other actions or services that bring additional value to entities and the government:

In addition to the value added products & services and the shareback, Apexus can bring value to the entities, manufacturers, and the government in other unique ways.

*Information Technology Infrastructure*

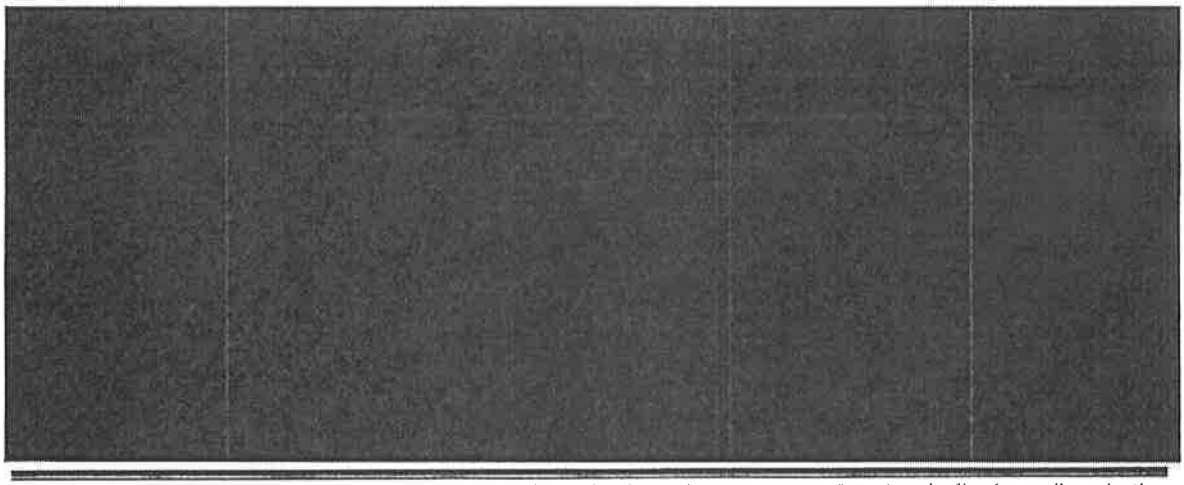
Apexus has created extensive interface technology with the HRSA membership database that creates an integrated, homogenous link between HRSA and the 340B PVP participant databases. Apexus has also worked and will continue to advance the 340B ceiling price pilot project for pricing transparency. Apexus would like to publish the 340B ceiling price file on our secure web site to improve program integrity in the future.

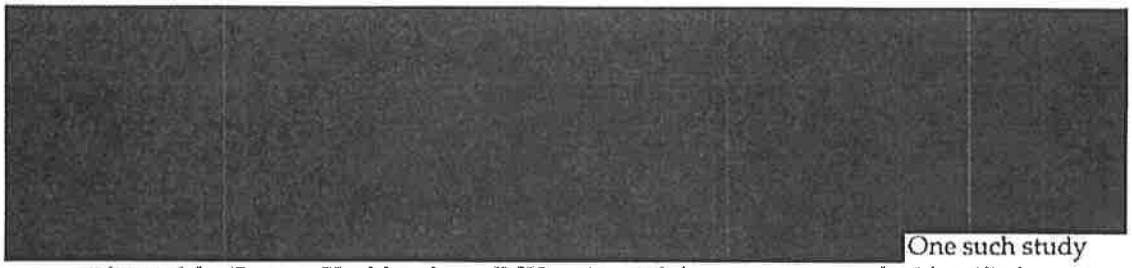
*CDC and State Departments of Health*

Apexus has and will continue to work with the CDC, HRSA, and their grantees to communicate treatment guidelines and report vaccination rates in the U.S. In addition to the CDC, Apexus has been instrumental in bringing value at the State Department of Health for its subgroup of entities and will continue to expand this role where applicable.

*Medicare Part D Contracting*

At the request of our DSH Advisory Council, Apexus formed a Medicare Part D subcommittee that discussed the need to represent the 340B community's in obtaining a better reimbursement rate with Member Health. In addition, securing better reimbursements, the committee helped create a contract that has worked for the entire 340B community for Medicare Part D. An example of this would be allowing DAW 5 reimbursement at a generic rate. This is a key facet for 340B entities as they use many branded drugs that are actually cheaper than their generic equivalents. Member health agreed to make changes in their contracts and systems to facilitate 340B entities because Apexus and its committee were able to represent the 340B entities unique needs collectively.





One such study was performed for Denver Health, a large DSH entity and the summary results identified a potential annual savings of over three million dollars. See below for details.

Figure 119: Denver Health Cost Savings Study: Q308

| Savings Potential from Q3 2008 Analysis | |
|---|---|
| Contract Loading Issues: | $17,767.21 |
| Generic Substitution: | $278,947.75 |
| Therapeutic Substitution: | $458,876.73 |
| Quarterly Savings: | $755,591.69 |
| Annualized Savings: = | $3,022,366.76 |

*Value for Manufacturers*

Apexus brings a value added services to its contracted suppliers by communicating any omissions or errors in their quarterly 340B price file loading at the wholesalers. If this omission or error were not identified early on, considerable resources would be required to process the thousands of chargebacks that would have to be processed later. In addition to this, Apexus is in negotiations with manufacturers to facilitate processing of historical overcharges of covered entities via a wholesaler credit to 340B pharmacy accounts. Some manufacturers have been sitting on credits to distribute because they are unsure of how to process them, or do not have current address information for entities to issue checks. Apexus could create a favorable solution for all parties via its unique, centric position in the 340B marketplace.

*Value for Wholesalers*

Distributors are in a difficult situation to try and administer the ever changing complex 340b price file. They constantly process chargebacks based on errors in billing covered entities. Apexus helps alleviate some this by providing a comparison file at the beginning of each pricing quarter. This file identifies outliers so that pricing omissions or errors can be resolved prospectively rather than after the fact when it takes twice the resources to correct.

*Educational Scholarships/ Grants*

Apexus is dedicated to improving education about 340B and ways that the program can help

extend care to more of the nation's indigent and working poor. The 340B PVP website now has an extensive tutorial on how to navigate the complexities of the program. This tutorial has been used by many participants, suppliers, and other healthcare parties to educate themselves about the program. Apexus also provides travel grants and scholarships for educational conferences for participants. These include scholarships for pharmacy buyers to attend purchasing conferences, funding for healthcare teams to travel to learning sessions related to the Patient Safety & Clinical Pharmacy Services Collaborative.

*Patient Safety & Clinical Pharmacy Services Collaborative*

The Patient Safety & Clinical Pharmacy Services Collaborative is the first national attempt to reduce medication errors and improve clinical outcomes using data based methodologies. Apexus will continue to support HRSA's PSPC in the following ways:

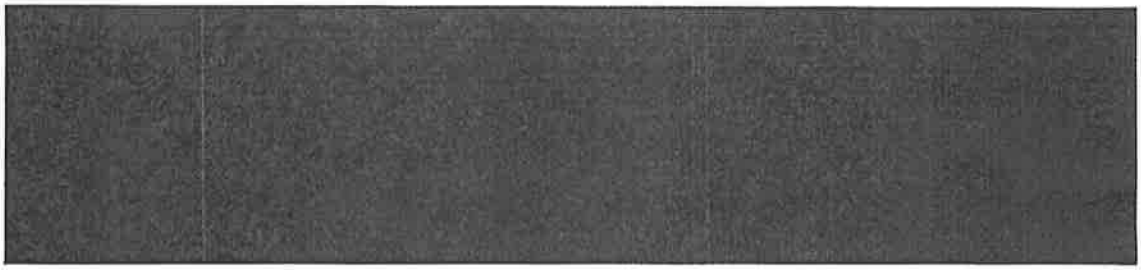
- Serving as a member of Leadership Council with other national organizations (APHA, ASHP, ORHP, JCAHO)
  - By promoting the message and success stories of the collaborative within these national organizations, the Prime Vendor is marketing the need and benefits of a safer medication delivery system.
  - Networking between these organizations allows creative dialog and original thought about changes to our delivery systems to increase efficiency and safety.
  - Bi-directional feedback is accomplished as we get guidance from our participants on barriers to implementation for some of the recommendations.

- Providing the ISMP Medication Safety Alert (Community - Ambulatory Care Edition) to all participants to support their own patient safety initiatives. The newsletter assists by the following:
  - Recommends methods to improve medication safety within a practice site.
  - Provides access to a unique tool to keep participants abreast of actual medication errors, contributing factors, and prevention suggestions that can help you reduce the risk of similar errors at your practice site.
  - Enables participants to practice the ultimate prevention by helping to protect patients, staff, and organizations from costly and life threatening medication errors.
  - Provides access to a Toll-free telephone access to ISMP for medication error prevention advice and in-depth information about reported problems.

- Co-sponsoring and funding of PSPC meetings/teams
  - In these difficult economic times, many teams have a hard time funding travel to the education sessions. The Prime Vendor has sponsored several of these teams that otherwise would not be financially able to participate.
  - The Apexus Board of Directors has agreed to continue its support of the PSPC teams and events in 2009.

- Supporting the Medication Safety and Effectiveness Health Education Initiative with the FDA's Office of Women's Health

- Apexus participants are entitled to download and/or order free publications specific to FDA related products. The benefits of these publications promote patient safety, health care quality, and positive health outcomes and include:
  - Sheets for Allergies, Asthma, Diabetes, Flu, Generic Drugs, Heart Disease, HIV, OTC Drugs, Sleeping Disorders, Stroke, and more.
  - Medication Booklets on Birth Control Guide, Depression, High Blood Pressure, Cholesterol, HIV and AIDS, and more.
  - Publications specific to Women's Health include Fact Sheets and Medication Booklets on HPV, Mammograms, Pap Tests, Taking Medicines While Pregnant, and more.
  - Other Publications including Birth Control Guide Posters, Diabetes Recipes cards, Menopause and hormones purse guides, and more.



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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEVADA**

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff,

– vs. –

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I – X and ROE CORPORATIONS I – X, inclusive,

Defendants.

Case No. 2:12-cv-01849-JCM-NJK

**DECLARATION UNDER PENALTY OF PERJURY OF JIMMY R. MITCHELL PURSUANT TO 28 U.S.C. § 1746**

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**DECLARATION UNDER PENALTY OF PERJURY OF JIMMY R. MITCHELL PURSUANT TO 28 U.S.C. § 1746**

I, JIMMY R. MITCHELL, hereby declare that:

1. My name is Jimmy R. Mitchell. I am of sound mind and have never been convicted of a felony. The facts stated in this declaration are true and correct, and are based upon my personal knowledge.

2. I graduated from the University of Mississippi School of Pharmacy in 1964 with a Bachelor's Degree in Pharmacy. I then obtained a Master's Degree in Public Health from Johns Hopkins University in 1972 and a Master of Science in National Resource Strategy-Healthcare Industry focus from the Industrial College of the Armed Forces, National Defense University, Fort McNair, Washington, DC in 1994. I have also taken courses related to training for my various job obligations with the US Public Health Service Corps from Harvard Business School, the Federal Executive Institute and national pharmacy organizations.

3. I joined the US Public Health Service Corps ("PHS") in 1967. My first assignment was as a pharmacy officer and later as the hospital administrative officer at the Indian Health Service Hospital on the Pine Ridge Indian Reservation in South Dakota. Other positions with the Indian Health Service included headquarters assignments as assistant to the Health Care Administration Branch Director and as Director of the Contract Health Services program. Other major PHS work included special assignment to chair Surgeon General C. Everett Koop's Revitalization Task Force on Professional Manpower Recruitment; Deputy Director of the National Hansen's Disease Program and later, as the Director of the Office of Pharmacy Affairs. I am currently an independent contractor, playing a leadership role in advancing medication safety initiatives within the safety-net community, under contract with Apexus.

4. I retired from the US Public Health Service Commissioned Corps as a Captain. My last post was as the Director of the Office of Pharmacy Affairs ("OPA") within the Health Resources and Services Administration ("HRSA"). Both the OPA and HRSA are housed within the Department of Health and Human Services. After retiring as a PHS Commissioned Officer, I continued as OPA Director as a GS-15 employee. I retired from federal employment August, 2010.

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5. I first was assigned to the OPA in the December, 1997. At that time, it was called the Office of Drug Pricing. I was appointed as the Interim Director for a short period of time, and later as the full-time Director. The mission of the Office of Drug Pricing was, in my opinion, to passively administer the Section 602 of the Veterans Health Care Act of 1992 (340B Public Health Service Act) which requires drug manufacturers to provide statutorily discounted prescription drugs to approximately 15,000 ambulatory cares safety-net providers. In addition to registering covered entities to participate in the Program, the ODP issued Federal Register guidelines to inform concerned parties (primarily covered entities and drug manufacturers) of the policies that the federal government wanted implemented to make the program work. The Office of Drug Pricing did not have a role in distribution or in price negotiations. I wanted the Office of Drug Pricing to be more proactive and help safety net organizations to develop their pharmacy programs. Many of the safety-net providers did not have or had very limited pharmacy programs. Accordingly, I proposed to my supervisor that the name and the mission of the office should be changed to improve pharmacy services within the safety-net organizations that were eligible to participate in the 340B Program. My proposal was subsequently approved by HRSA and the name of the Office of Drug Pricing was changed to the Office of Pharmacy Affairs (OPA) with a new mission of activity promoting access to clinically and cost effective pharmacy services.

6. At the time of the formation of the OPA, an estimated 15,000+ "covered entities" that purchased over $6 billion in discounted drugs annually included much of the nation's safety net providers, such as, disproportionate share hospitals; community and migrant health centers; HIV/AIDS programs; comprehensive hemophilia treatment centers, children's hospitals, critical access hospitals, etc. Responsibilities of the new OPA included provision of national pharmacy leadership to these covered entities; the development of policies, regulations and budgets; coordination of policies with drug manufacturers, drug wholesalers and covered entities to achieve "best buy strategies": negotiating the lowest possible price for covered drugs and other value added products; implementation of efficient pharmacy systems and a focus on maximizing patient outcomes through safe and effective medication use.

7. Major accomplishments of the OPA before I retired included: implementation of a national drug rebate program for State AIDS Drug Assistance Programs; implementation of a national prime vendor program that includes drug distribution, price negotiation and other related value added products and services; implementation of several pharmacy demonstration projects to improve patient access to pharmaceuticals and pharmacist's care; the development of the Pharmacy Services Support Center through a multiyear contract with the American Pharmacists Association under which technical assistance was provided to safety-net organizations that wanted to implement comprehensive pharmacy services; and the Patient Safety and Clinical Pharmacy Services Collaborative to improve patient safety and outcomes through comprehensive medication management.

8. The Veterans Health Care Act of 1992, Section 602 (the 340B Public Health Service Act) required the 340B Program to include a Prime Vendor, but it failed to define what function a prime vendor was to perform. To gain insight into what duties a prime vendor was to perform, the OPA staff looked at the Veterans Administration's very successful program that was also covered by the Veterans Health Care Act of 1992, Section 601. The Veterans Administration's overall program included price negotiations, product distribution and certain other products and services.

9. The OPA was unlikely to ever have the resources to implement a federally staffed prime vendor program like the one operated by the Veterans Administration. The OPA then proposed that HRSA solicit a no-cost contract for prime vendor services under 340B. The proposed 340B Prime Vendor would manage the Prime Vendor Program for HRSA and would be required to offer products and services that mimicked certain products and services offered by the Veterans Administration's Prime Vendor.

10. To mimic the Veterans Administration's program that was primarily provided by federal staff and federal funds, the OPA's Prime Vendor needed to be a public-private partnership. The OPA at the time had a very small staff of less than a dozen. It needed a partner within the private sector to offer the range of products that the safety net organizations wanted and needed but

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that the federal government could not provide within the resources it had to implement the requirement that there be a 340B Prime Vendor Program.

11. HRSA signed the original five year Prime Vendor contract in 1999 with AmerisourceBergen ("AMB"), one of the three largest national wholesale drug distributors. It had the range of products and services desired by the safety net organizations, but it soon demonstrated that it lacked capacity to perform in two key areas in the market-place as the 340B Prime Vendor: the capacity to negotiate 340B sub-ceiling prices with brand named drug manufacturers and the capacity to contract with other wholesale drug distributors that could serve the large number and varied 340B covered entities. Accordingly and with the government's approval, in 2004 AMB outsourced the Prime Vendor role to HPPI, which is the precursor to Apexus, which had the needed expertise that ABM lacked.

12. After it was retained as AMB's subcontractor, HPPI (at that time) implemented the provisions of the Prime Vendor Agreement that required the set up of Customer Consultation Groups from among the 340B safety net organizations, which are also called "covered entities" under the 340B program. In the Customer Consultation Groups, the covered entities could discuss issues they had with the 340B program and also suggest changes. One of the key issues that the covered entities raised time and again was the need for the 340B program to provide access to low cost vaccines.

13. Because of the demands of the Customer Consultation Groups with regard to vaccines, Apexus approached me and asked if it could begin negotiating with the pharmaceutical companies to include vaccines for Prime Vendor participants even though vaccines were not considered 340B outpatient covered drugs. After consulting OPA's legal counsel and HRSA contract management staff, HRSA responded that, in light of the Prime Vendor contract terms, Apexus could include vaccines if they were included as a part of the value added products, and if vaccine manufacturers voluntarily offered their products. Neither the Prime Vendor nor OPA could compel manufacturers to offer their products, even though their products benefited the public

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health. Apexus approached the pharmaceutical companies and they agreed to sell vaccines through the 340B Prime Vendor Program at voluntary discounts

14. Importantly, the Veterans Administration's Prime Vendor Program includes vaccines, which are critical for any type of preventative care program. The only way to provide vaccines under the 340B Prime Vendor Program was to include these products as part of the Value Added Products provided by the Prime Vendor. Including vaccines in the 340B Prime Vendor Program as Value Added Products was rationally related to the OPA's mission. Further, it was reasonable because it aligned the 340B Prime Vendor Program with the Veterans Administration's model, which OPA had used as a template.

15. When AMB's contract ended in 2004, OPA, through HRSA, conducted an open, competitively bid process for a new five year Prime Vendor contract. As part of the terms of this new solicitation, HRSA included a section related to Optional Services and Catalog Items. HRSA had not offered such a section during the initial contract's bid process in 1999. At that time, however, AMB had included Value Added Products as an extra in their contract proposal in response to the initial solicitation, and HRSA accepted them. The covered entities appreciated the benefits that the additional products and services had provided, and wanted more. Accordingly, in order to try and meet the demands of the covered entities, as expressed through the Customer Consultation Groups organized by Apexus, HRSA added the section called Optional Services and Catalog Items to the 2004 solicitation. In its 2004 proposal submission, Apexus offered to include vaccines as part of the Optional Services and Catalog Items. Apexus was ultimately awarded the 2004 contract and as per the contract terms, vaccines were offered through the Prime Vendor Program beginning in 2005. In 2007, HPPI transferred the contract to a new, successor company, Apexus, Inc., (a subsidiary of a related company Provista, Inc.) and Apexus has served in the Prime Vendor role ever since.

16. In the 2009 solicitation, HRSA changed the name of the Optional Services and Catalog Items section to the Value Added Products Section. In the 2009 Solicitation, HRSA used

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vaccines as the example of a Value Added Product. Among other value added products or services, Apexus again offered to include vaccines as part of its proposal.

17. Neither I nor my team at OPA evaluated the bids offered in response to the new solicitation from the competing companies to be Prime Vendor. The bids were all reviewed by HRSA's Procurement Office and an independent review committee. The independent review committee recommended that the 2009 Prime Vendor Contract be awarded to Apexus, which had the most responsive proposal.

18. Because Apexus had included vaccines as part of its value added products under its proposal in response to the 2009 solicitation, and HRSA had awarded it the contract, it had to offer vaccines during the contract term. Accordingly, Apexus continued its negotiations with the pharmaceutical companies, such as GlaxoSmithKline, and secured the provision of numerous vaccines for the covered entities to purchase through the 340B Prime Vendor Program.

19. While the 340B program does not specifically include vaccines as covered drugs under the statute, nothing prohibits the sale of vaccines under the Prime Vendor Program. This makes sense and is rationally related to the goals of the Prime Vendor Program and the 340B program. Vaccines are an integral piece of the public health care system. Allowing safety net organizations to have access to low cost vaccines helps ensure that all members of the public are vaccinated against key diseases, like flu, hepatitis A & B, diphtheria, tetanus, pertussis, polio and others. Providing covered entities with access to low cost vaccines helps prevent the spread of diseases, many of which would cost the public health system in the US significant funds to treat and cure. This decision is consistent with the mission of the OPA and HRSA as well as prior and subsequent actions by OPA and HRSA in treating the poor and under-served of the United States. As a result, vaccines provide added value to the 340B program and are a benefit to public health. It makes sense to include them as part of the products offered to the covered entities.

20. The OPA's and HRSA's decision to include the sale of vaccines under the 340B Prime Vendor Program was within the scope of their authority. Moreover, the decision to include

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vaccines was based upon the value added to the 340B program and the legitimate need for the inclusion of vaccines.

21. In general covered entities are relatively small, such as state or county health districts, DSH-hospitals, Federal Qualified Health Centers and other nonprofit healthcare providers. They generally do not have the resources that for-profit providers do. Also, their patients are often poor and uninsured and care is often provided without compensation or on a sliding fee based on ability to pay. The covered entities' ability to purchase discounted vaccines helps to further their mission as well as the mission of the Office of Pharmacy Affairs and the 340B Program—to promote access to clinically and cost effective pharmacy services; improving public health while serving the poorest members of the community.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22nd day of July, 2014, at Falls Church Virginia.

Jimmy R. Mitchell

Submitted by:

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# EXHIBIT D

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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEVADA**

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff,

– vs. –

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I – X and ROE CORPORATIONS I – X, inclusive,

Defendants.

Case No. 2:12-cv-01849-JCM-NJK

**DECLARATION UNDER PENALTY OF PERJURY OF GREGORY J. CASAS PURSUANT TO 28 U.S.C. § 1746**

**DECLARATION UNDER PENALTY OF PERJURY OF GREGORY J. CASAS PURSUANT TO 28 U.S.C. § 1746**

I, GREGORY J. CASAS, hereby declare that:

1. My name is Gregory J Casas and I am one of the counsel of record for Apexus, Inc. in this suit. I am of sound mind and competent to issue this declaration. The facts stated below are true and correct and within my personal knowledge.

2. Attached to this motion as Exhibit A is a true and correct copy of the Agreement between the Health Resources and Services Administration and Apexus, Inc., granting Apexus the exclusive contract to be the 340B Prime Vendor for the period 2009 through 2014. This document was provided to me by Apexus by the person whose job responsibilities include obtaining such documents at or near the time of their creation and execution and keeping of such documents.

3. Attached as Exhibit B to this motion are true and correct excerpts of Apexus's HRSA 340B Prime Vendor RFP Response to Solicitation provide by Apexus to the 2009 Solicitation. As per the Court's Order, (Dkt. # 102 and 105) certain information has been redacted. Someone under my supervision made these redactions. We received the document from Apexus in its entirety and in unredacted form. This document was provided to me by Apexus by the person whose job responsibilities include obtaining such documents at or near the time of their creation and execution and keeping of such documents.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22nd day of July, 2014, at Austin, Texas.

Gregory J. Casas

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